УЛУЧШЕНИЕ ГЛИКЕМИЧЕСКОГО И ЛИПИДНОГО КОНТРОЛЯ У ПАЦИЕНТОВ С СД2 С ПОМОЩЬЮ ИНДИВИДУАЛЬНОЙ РАСШИРЕННОЙ ПРОГРАММЫ

© A. Theeranut, N. Methakanjanasak, P. Surit, W. Ruaisungnoen, K. Sawanyawisuth, D. Saensom

Khon Kaen University, Кхонкэн, Таиланд

ЦЕЛЬ. Оценить краткосрочные эффекты программы для контроля гликемического и липидного профиля в стационарных условиях у пациентов с сахарным диабетом 2 типа (СД2).

МЕТОДЫ. Данная работа представляет собой квази-экспериментальное исследование, проведенное в период с октября 2013 г. по июнь 2015 г. В него были включены поступившие в больницу пациенты с СД2 старше 35 лет и при уровне HbA_{1c} >7%. Во время пребывания в больнице экспериментальная группа три раза до выписки прошла курс расширенной программы контроля, тогда как в отношении контрольной группы проводились стандартные мероприятия по уходу за пациентами с СД2. Вес всех пациентов, уровень HbA_{1c}, холестерина ЛПВП и ЛПНП оценивали через 3 и 6 мес после выписки. Все результаты сравнивались между контрольной и экспериментальной группами.

РЕЗУЛЬТАТЫ. В исследовании участвовали 57 пациентов с СД2, из которых 27 были в экспериментальной группе и 30 – в контрольной группе. В экспериментальной группе были значительно более высокие уровни HbA_{1c}, чем в контрольной группе (10,3% vs. 8,0%, p<0,001). После выписки средние уровни HbA_{1c} и холестерина ЛПНП в экспериментальной группе были значительно ниже, чем в контрольной группе через 3 и 6 месяцев, тогда как через 6 месяцев средний уровень холестерина ЛПВП в экспериментальной группе был значительно выше, чем в контрольной группе (1,54 vs. 1,29 ммоль/л, p<0,001). Средний индекс массы тела в экспериментальной группе также был значительно ниже, чем в контрольной группе через 6 мес (22,74 vs. 25,54 кг/м^2, p=0,016).

ЗАКЛЮЧЕНИЕ. Индивидуальная расширенная программа контроля позволила улучшить краткосрочные показатели гликемии и липидов у поступивших пациентов с сахарным диабетом.

КЛЮЧЕВЫЕ СЛОВА: поведение; гемоглобин A_{1c}; холестерин липопротеинов низкой плотности; холестерин липопротеинов высокой плотности

THE INDIVIDUAL EMPOWERMENT PROGRAM IMPROVES GLYCEMIC AND LIPID CONTROLS IN ADMITTED TYPE 2 DM PATIENTS

© Ampornpan Theeranut, Nonglak Methakanjanasak, Pattama Surit, Wasana Ruaisungnoen, Kittisak Sawanyawisuth, Donwiwat Saensom

Khon Kaen University, Khon Kaen, Thailand

AIM. To evaluate the short-term effects of the empowerment program on glycemic and lipid profiles in an inpatient setting for DM type 2 patients.

MATERIALS AND METHODS. This was a quasi-experimental study conducted between October 2013 and June 2015. We enrolled diabetes patients admitted to the hospital, age over 35 years, and HbA_{1c} > 7%. During the admission, the intervention group received the empowerment course three times prior to discharge, the control group received standard diabetes and nursing care. All patients' body weight, HbA_{1c}, HDL-c, and LDL levels were evaluated at three and six months after discharge. All outcomes were compared between the control and intervention group.

RESULTS. A total of 57 diabetes patients participated in the study, with 27 in the intervention group and 30 in the control group. The intervention group had significantly higher HbA_{1c} levels than the control group (10.3% vs 8.0%; p value < 0.001). After discharge, the mean HbA_{1c} and LDL-c levels of the intervention group were significantly lower than those of the control group at three and six months, while the mean HDL-c level of the intervention group was significantly higher than that of the control group at six months (1.54 vs 1.29 mmol/L; p value <0.001). The average body mass index of the intervention group was also significantly lower than that of the control group at six months (22.74 vs 25.54 kg/m^2; p value = 0.016).

CONCLUSION. The individual empowerment program improved short-term glycemic and lipid outcomes in admitted diabetes mellitus patients.

KEYWORDS: behaviors; hemoglobin A_{1c}; low-density lipoprotein cholesterol; high-density lipoprotein cholesterol

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BACKGROUND

Type 2 diabetes mellitus and dyslipidemia are major risk factors for cardiovascular diseases and mortality [1, 2]. Although the prevalence of dyslipidemia in diabetes patients is not higher than in patients without diabetes (9% vs 11% in men and 15% vs 16% in women) [3], the American Diabetes Association recommends lifestyle intervention in all diabetes patients [4]. The desirable LDL goal is < 100 mg/dL or 2.6 mmol/L in diabetes patients without cardiovascular disease [4]. Good glycemic control with less than seven percent HbA_{1c} is associated with lower microvascular complications in diabetes patients by 12% or relative risk of 0.88 [5]. Intensive glycemic control may also lead to improved macrovascular outcomes, such as a 16% reduction in myocardial infarction [7].

In addition to hypoglycemic and lipid-lowering agents, lifestyle modification is another crucial factor for diabetic patients in achieving good glycemic and lipid control [7–10]. The educational program for diabetes or empowerment method, when employed in conjunction with standard medications, is associated with reductions in HbA_{1c} and LDL cholesterol. A one-year study found that a group empowerment program reduced HbA_{1c} levels by 0.6% [11]. Six out of nine studies (66.7%) in the meta-analysis showed significant reduction in HbA_{1c} [10]. The effects of the empowerment program on LDL-c are controversial. A study from the US found that the LDL levels decreased by 15 mg/dL during a 15-month group empowerment program with peer support [7]. However another study found no difference in LDL levels between diabetic patients that underwent an empowerment program and those who did not (142 vs 166 mg/dL; p value 0.081) [12]. Both studies were performed in community care settings. This study aimed to evaluate the short-term effects of the empowerment program on glycemic and lipid profiles in an inpatient setting.

MATERIALS AND METHODS

This was a quasi-experimental study conducted at Srinagarind Hospital, a university hospital of Khon Kaen University. The study period was between October 2013 and June 2015. The inclusion criteria were type 2 diabetes patients admitted to the hospital (Internal Medicine ward) who were over 35 years of age and had HbA_{1c} levels of over 7%. Patients were excluded if they had any critical conditions, required mechanical ventilation, suffered from physical or emotional instability, or were unable to complete the study protocol. This study was a part of the Diabetes Empowerment Project.

Eligible patients underwent purposive sampling by a nurse involved in the study. The first 30 patients to be enrolled were assigned to the control group, and the latter 30 patients were assigned to the intervention group. The control group received standard diabetes and nursing care during the admission period. The intervention group received similar care to the control group and in addition, were enrolled in an empowerment program. The empowerment program consisted of 4 steps including 1. building patient self-awareness and the ability to assess their own health needs and problems, 2. implementing nursing interventions to empower the patients, 3. evaluating outcomes, and 4. monitoring and supporting patient empowerment.

To build participants' self-awareness, the nurses used a self-reflection technique in which participants identified their own problems and needs. The empowerment need assessment tool was used to identify the problems related to diabetes care. It includes factors such as the progression of the disease, symptoms and complications, medication compliance, diet control, exercise, stress and coping, foot care, and additional problems.

In order to empower the patients, nursing intervention provided through printed material which covered diabetes pathology, treatments, diabetic complications, diet control, exercise, medication compliance, stress management, foot care, and management of other risk factors. The patient-centered approach was used to promote self-care, decision making, goal setting, and practice of the patients. Each patient identified and ranked their own problems individually. The three top-ranked problems were corrected by the nurses. The nurses, who were trained by nurses specializing in diabetes treatment, acted as coordinators and supporters. The instruction was carried out on an individual basis with no time limitation three times prior to discharge. The nurses discussed problems with the patients after discharge before the three and six-month follow-ups. The three nurses who participated in this study all had Master of Science in Nursing. Figure 1 summarized the empowerment steps.

At the beginning of the study, data regarding baseline characteristics, HbA_{1c}, HDL-c, and LDL-c were collected. All patients' body weight, HbA_{1c}, HDL-c, and LDL levels were evaluated at three and six months after discharge. All patients received standard of care by the attending physicians in terms of medications and compliance monitoring.

Sample size calculation. Based on the previous study [12], the empowerment program and control group had average (SD) HbA_{1c} of 7.75% (1.29) and 8.61% (1.55), respectively. With a power of 80% and 90% confidence interval, the required sample size was 25 patients in each group. A 10% of missing data in each group was also added.

Statistical analyses. All baseline characteristics and outcomes were compared between the control and intervention group using descriptive statistics. An independent t-test was used to compare between the two groups if data were normally-distributed, and a Wilcoxon rank sum test was used if data were not normally distributed. The Chi square or Fisher Exact test was used to compare proportions between the two groups. The differences were considered to be statistically significant at $p < 0.05$. All analyses were performed using the Statistical Package for the Social Sciences (SPSS) for Windows version 10.0 (College Station, Texas, USA).

Ethical consideration. The study protocol was approved by the ethic committee in human research, Khon Kaen University, Thailand (HE551348).

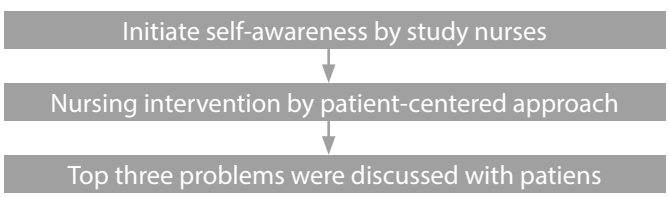

Fig 1. The empowerment program for admitted diabetic patients.

Table 1. Baseline characteristics of diabetes patients categorized by group of treatment

Factors	Intervention group (n = 27)	Control group (n = 30)	p value
Age (year)	59.9(10.1)	59.4(10.5)	0.854
Male sex, n (%)	5(8.8)	13(22.8)	0.052
Diabetes duration (year)	9.6(5.8)	13.5(8.9)	0.010
BMI (kg/m^2)	23.2(5.8)	25.3(4.9)	0.150
HbA_{1c} (%)	10.3(2.2)	8.0(1.8)	<.001
HDL-c, mg/dL	1.2 (0.3)	1.2 (0.5)	0.830
LDL-c, mg/dL	3.2 (0.9)	3.5 (1.5)	0.310
Treatment			
Diet therapy, n (%)	1 (3.70)	8 (36.67)	0.027
Sulfonylurea, n (%)	15 (55.56)	6 (20.00)	0.007
Metformin, n (%)	13 (48.15)	8 (26.67)	0.108
Insulin, n (%)	14 (51.85)	13 (43.33)	0.600

Notes: data presented as mean (SD) unless indicated otherwise; BMI: body mass index; HbA_{1c}: Hemoglobin A1C; HDL-c: High-density lipoprotein cholesterol; LDL-C: Low-density lipoprotein cholesterol.

RESULTS

A total of 57 diabetes patients participated in the study, with 27 in the intervention group and 30 in the control group. Both groups had comparable baseline characteristics with the exception of duration of diabetes and HbA_{1c} levels (Table 1). The intervention group had significantly higher HbA_{1c} levels than the control group (10.3% vs 8.0%; p value < 0.001) and had higher proportions of patients taking sulfonylurea (55.56% vs 20.00%; p value 0.007).

After discharge, the mean HbA_{1c}, HDL-c, and LDL-c levels were significantly lower in the intervention group than in the control group (Table 2-4). The mean HbA_{1c} and LDL-c levels of the intervention group were significantly lower than those of the control group at three and six months (Table 2 and 4), while the mean HDL-c level of the intervention group was significantly higher than that of the control group at six months (1.54 vs 1.29 mmol/L; p value <0.001), as shown in Table 3. The average body mass index of the intervention group was also significantly lower than that of the control group at six months (22.74 vs 25.54 kg/m^2; p value 0.016), as shown in Table 5.

This study showed that the inpatient empowerment program significantly improved both glycemic and lipid levels in diabetes patients (Table 2-4). Even though the program was performed only three times by nurses not specializing in diabetes treatment, the effects of the empowerment program on HbA_{1c} and LDL-c levels lasted for six months, with initial effects at three months (Table 2 and 4). This program was conducted only three times in a hospital setting by nurses not specializing in diabetes treatment and dealt with the three issues that were highest ranked by the patients, themselves. This was a patient-centered individual approach.

Patients' HbA_{1c} levels after the empowerment program were significantly lower than those of patients in the control group (7.4% vs 8.8%; p value < 0.001), as shown in Table 2.

Table 2. HbA_{1c} levels of diabetes patients categorized by treatment group at various times

Times	Intervention group (n = 27)	Control group (n = 30)	p
	Mean (S.D)	Mean (S.D.)	
Baseline	10.30(2.20)	8.00(1.80)	<.001
3 months after discharge	7.50(0.90)	8.40(1.30)	<.001
6 months after discharge	7.40(0.70)	8.80(1.10)	<.001

Table 3. HDL-c levels of diabetes patients categorized by treatment group at various times

Times	Intervention group (n = 27)	Control group (n = 30)	p
	Mean (S.D)	Mean (S.D.)	
Baseline	46.10(13.40)	47.00(18.70)	0.830
3 months after discharge	57.80(10.60)	50.80(16.70)	0.070
6 months after discharge	59.60(12.30)	49.70(10.50)	<.001

Table 4. LDL-c levels of diabetes patients categorized by treatment group at various times

Times	Intervention group (n = 27)	Control group (n = 30)	p
	Mean (S.D)	Mean (S.D.)	
Baseline	124.20(34.20)	137.00(58.50)	0.310
3 months after discharge	98.10(18.40)	139.50(46.00)	<.001
6 months after discharge	94.20(16.80)	142.80(32.30)	<.001

Table 5. Body mass indices of diabetes patients categorized by treatment group at various times

Times	Intervention group (n = 27)	Control group (n = 30)	p
	Mean (S.D)	Mean (S.D.)	
Baseline	23.19	25.27	0.146
3 months after discharge	22.87	25.76	0.025
6 months after discharge	22.74	25.54	0.016

This is despite the fact that the baseline HbA_{1c} levels of the empowerment group were significantly higher than those of the control group (10.3% vs 8.0%; p value < 0.001). By the end of the study, the HbA_{1c} levels of the empowerment group had nearly reached those of good glycemic control as also reported in other studies [7, 12, 13]. The average HbA_{1c} levels after the empowerment program in previous studies from Iran and the US were 7.7% and 7.3%, respectively.

Patients' HDL-c levels after the empowerment program slowly increased and differed significantly from those in the control group at six months (1.54 vs 1.29 mmol/L), as shown in Table 3. These findings were consistent with those of two other studies, one from Iran and one from the US [7, 12]. The study from Iran showed significant improvement in HDL-c levels after eight weeksof group typed empowerment program (1.29 vs 1.11 mmol/L; p value < 0.001) compared with a control group [12]. The study from the US showed longer lasting effects of the empowerment program, with HDL-c levels increases of 14 mg/dL after 15 months [7]. In this study, HDL levels had increased by 0.34 mmol/L at six months after the program's completion (Table 3).

As mentioned in the introduction, the effects of empowerment program on LDL-c levels are the subject of debate [7, 12]. This study found that the LDL-c levels were significantly lower in the empowerment group than in the control group (Table 4). This difference was statistically significant at three and six months. Although the empowerment group in the Iran study did not show a significant reduction of LDL-c levels [12], patients in that group did have lower average LDL-c levels (3.67 vs 4.30 mmol/L). Note that the Iran study evaluated LDL-c levels at three months after the empowerment program. If the author had checked LDL-c levels again at six or 15 months, it may have shown significant results similar to the study from the US and this current study [7].

The benefits of the empowerment program found in this and other studies may have been due to weight loss on the part of the patients [14-16]. The average body mass index of patients in the empowerment group in this study was 2% (Table 5). A 5% weight reduction and a 2.82% body mass index reduction has been shown to be linked with decreases in LDL-c levels of 0.45 mmol/L and increases in HDL-c levels of 0.07 mmol/L [16]. The empowerment program's effect on bodyweight is controversial [17, 18]. Patients had an average body mass index reduction significantly from 34.7 to 34.2 kg/m^2 ($p < 0.05$) at six months after the empowerment program [17], which is similar to the results of this study (22.74 vs 25.54 kg/m^2; p value 0.016), as shown in Table 5. In another study however, there were no improvements with regard body mass index at one year [18].

There were some limitations in this study. First, the outcomes were evaluated after 6 months of the program. Further longer evaluations should be performed. Second, the baseline HbA_{1c} in the intervention group was significantly higher than the control group due to non-randomized study design. In other words, the intervention group had more uncontrolled diabetes patients and required more medications particularly sulfonylurea (55.56% vs 20.00%; p value 0.007) as shown in Table 1. However, the intervention was significantly reduced the HbA_{1c} level (Table 2). Note that even though we did not have data on anti-diabetic medications at the end of the study, all patients received standard of care in terms of medications. Additionally, reasons of hospitalization, diabetic complications, and co-morbidities were not recorded. However, these diabetic patients admitted and enrolled in this study were not in severe clinical conditions. Third, the triglyceride level was not measured due to low effects on cardiovascular diseases at the beginning of the study. Fourth, the study nurses were all had Master of Science in Nursing. Further studies conducted by other levels of nurses may be needed. Finally, the study nurses were all had Master of Science in Nursing. Further studies conducted by other levels of nurses may be needed.

CONCLUSION

The individual empowerment program had potential to improve short-term glycemic and lipid outcomes in admitted diabetes mellitus patients.

ADDITIONAL INFORMATION

Conflicts of interest. The authors declare no conflicts of interest.

Authors involvement. Ampornpan Theeranut: study design, data collection, data interpretation, draft a manuscript.

Nonglak Methakanjanasak, Pattama Surit, Wasana Ruaisungnoen: study design, data collection, data interpretation.

Kittisak Sawanyawisuth: data interpretation, statistical analysis, draft a manuscript.

Donwiwat Saensom: study design, data collection, statistical analysis, data interpretation, draft a manuscript.

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ИНФОРМАЦИЯ ОБ АВТОРАХ [AUTHORS INFO]

Donwiwat Saensom, PhD, RN, Department of Adult Nursing, Faculty of Nursing; address: 123 Moo 16 Mittapap Rd., Nai-Muang, Muang District, Khon Kaen 40002,Thailand; ORCID: https://orcid.org/0000-0002-7317-3741; e-mail: donsae@kku.ac.th

Ampornpan Theeranut, RN, PhD, Associate Professor, Department of Adult Nursing, Faculty of Nursing and acting director of Research and Training Center for Enhancing Quality of Life of Working Age People, Khon Kaen University, Khon Kaen, 40002, Thailand; ORCID: https://orcid.org/0000-0003-0580-3518; e-mail address; amptee@kku.ac.th
Nonglak Methakanjanasak, RN, PhD, Assistant Professor, Department of Adult Nursing, Faculty of Nursing, Khon Kaen University, Khon Kaen, 40002, Thailand ORCID: https://orcid.org/0000-0001-7642-7586; e-mail address; mnonglak@kku.ac.th
Pattama Surit, RN, DNS, Assistant Professor, Department of Adult Nursing, Faculty of Nursing, Khon Kaen University, Khon Kaen, 40002, Thailand; ORCID: https://orcid.org/0000-0003-0070-7340; e-mail address; pattama@kku.ac.th
Wasana Ruaisungnoen, RN, PhD, Assistant Professor, Department of Adult Nursing, Faculty of Nursing, Khon Kaen University, Khon Kaen, 40002, Thailand; ORCID: https://orcid.org/0000-0002-4636-5270; e-mail address; waskir@kku.ac.th
Kittisak Sawanyawisuth, MD, MAS, PhD, MHPE, Professor, Department of Medicine, Faculty of Medicine, Khon Kaen University, Khon Kaen, 40002, Thailand; ORCID: https://orcid.org/0000-0003-3570-8474; e-mail address; kittisak@kku.ac.th
Donwiwat Saensom, RN, PhD, Assistant Professor, Department of Adult Nursing, Faculty of Nursing, Khon Kaen University, Khon Kaen, 40002, Thailand; ORCID: https://orcid.org/0000-0002-7317-3741; e-mail: donsae@kku.ac.th

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