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A Pilot Study to Test Feasibility the Effect Structured Education Program in Patients with Diabetes Kidney Disease

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Abstract

Background: Multidisciplinary team and education programs need to be set up for the treatment of complications related to diabetes.

Purpose: We aimed to test a structured educational intervention coordinated by diabetes nurse educator to improve self-management of diabetes in people with diabetic kidney disease.

Methods: Patients were randomly assigned to the control group to receive standard clinical management of diabetes with kidney disease or intervention group to receive the structured education. The primary endpoint was the change of renal function and metabolic parameters at 6th month.

Results: The control of HbA1c to level of <7% was achieved in 40% and 10% in intervention and control group, respectively. The percentage of achieving low-density lipoprotein cholesterol < 100 mg/dl increased by 31.25% and 6.25% in intervention and control group, respectively. The percentage of achieving systolic blood pressure to <130 mmHg was also increased. At 6 months, 30% attained 3 targets in intervention group, whereas 10% attained 3 targets in the control group. Intervention group significantly improved urine albuminuria status, regression of macro- or microabuminuria to normoalbuminuria occurred in 31.25% and 11.25% in intervention and control group, respectively.

Conclusion: Type 2 diabetes with diabetes kidney disease receiving a structure education program delivered by diabetes educator team is more likely to attain multiple treatment targets, by accepting treatment changes, and improved their self-care behaviors.

Keywords: Education; Diabetes kidney disease; Urine albumin creatinine ratio

Introduction

Chronic kidney disease (CKD) is becoming a major health concern worldwide and diabetes is one of the leading causes of dialysis worldwide. Diabetic kidney disease is the leading cause of end-stage renal disease (ESRD) worldwide [1]. The prevalence of diabetic kidney disease (DKD) has been increasing and differed from many ethnicities, with the greatest prevalence found in Asians population [2-5]. The main cause of the increases in prevalence and incidence of end-stage renal disease (ESRD) in Taiwan is probably related to the increased prevalence of DKD [6,7]. An analysis of the Taiwan nationwide data, the prevalence of DKD increased from 13.3% in year 2000 to 15.4% in year 2009. The corresponding diabetes dialysis rate has increased by approximately 1% during the same period [8]. The best health policy for reducing the cost of DKD is preventing its progression. The Steno-2 study has demonstrated that multifactorial intensified treatment, which include hemoglobin A1c (HbA1c), blood pressure (BP), and low-density lipoprotein cholesterol (LDL-C) results in a significant decrease of DKD [9]. Observation study demonstrated attainment of more than two treatment goals was associated with a 30-50% risk reduction in new onset cardiovascular disease [10]. Another prospective study showed multiple targets attainment directed to a significant reduction in new-onset microalbuminuria in type 2 diabetes [11]. According to these results, multifactorial intervention is important in prevention of diabetes complications like DKD. However, in real-world clinical practice, simultaneous achievement of these targets is low. Nurses, medical professionals, dieticians, and pharmacists are required to manage diabetes mellitus effectively, in particular in those with complications. Health care centers need to set up multidisciplinary teams for the management of diabetes chronic complications. Structured education programs that are designed to target these complications and multifactorial treatment attainments should now be made mandatory. Patients with DKD are cared by all areas of outpatient departments and diabetes nurse educator serve the coordinator for needs of this patient population. The purpose of this study is to test a structured educational intervention directed by diabetes nurse educator to improve self-management of diabetes in people with DKD.

Methods

Participants

Participants were recruited from January, 2013 to July, 2014; at endocrinology and diabetes outpatient clinics in a single study center. Patients with DKD had been referred to diabetes education center for DKD self-management care education.

Interventions

The control group received standard clinical management of diabetes and CKD. The participants were all treated under the Diabetes Shared Care System and CKD-integrated program system implemented in Taiwan since 1996 and 2011, respectively. Diabetes Shared Care System and CKD-integrated program system was provided by a diabetes team which includes specialist on diabetes and/

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or nephrologist and certified diabetes educators (nurses and dietitians). The care provided includes medical history, physical examination, laboratory test, management plan assessment, as well as diabetes and CKD self-management education (such as instruction on nutrition diet, physical activity, medication, complications prevention strategies, and self-monitoring of blood glucose and blood pressure).

The intervention group received a structured diabetes education intervention in addition to Diabetes Shared Care System and CKD-integrated program system standard care. The structured diabetes education program was provided in a two hour session every week for four weeks. The group education was coordinated by one certified diabetes nurse educator. The structured diabetes education program comprises of illustrated pictures that are used as a tool to engage small groups of patients. The illustrated picture could provide an interactive verbal and visual learning experience. The sessions delivered include the following topics: "Understanding the Many Factors of Managing Diabetes"; "How Diabetes Works; Living With Diabetes"; and "Healthy Eating and Being Active". In particular for the session of "Understanding the Many Factors of Managing Diabetes", it describes the natural course of diabetes and the long-term chronic complications. We also emphasize on the importance of multifactorial interventions for the prevention of diabetes complications, such as DKD.

In the control, group education was not delivered for participants. Instead, they receive one-to-one education sessions during every clinic visit. Diabetes patient education is usually provided using a preprinted education tool material such as a case report book covering assessment items and treatment targets. The time spent on education was based on individual's need.

Inclusion and exclusion criteria

Eligible participants were recognized for inclusion in the study if they had impaired renal function (estimated glomerular filtration rate (eGFR) <90 ml/min/1.73 m^2) and urine creatinine albumin ratio (UACR) > 30 mg/g at clinic visits in the previous 12 months. Pregnant women, patients with eGFR <15 ml/min/1.73 m^2, unable to give informed consent and aged <20 years were excluded.

Outcome measure

The primary endpoint was the percentage of patients who achieve hemoglobin A1c (HbA1c) less than 7%, systolic blood pressure (SBP) less than 130 mmHg, and low-density lipoprotein cholesterol (LDL-C) less than 100 mg/dl goals at 6th month. Secondary outcomes included the changes in metabolic profile, the percentage of patients who had progression of UACR and eGFR, and self-care behavior changes.

General demographic data were collected by the participants' physicians. All data were collected at baseline, the 3rd and 6th month, except questionnaire data were collected at the beginning of the study and at the 3rd month. Questionnaires collected included *Patient Health Questionnaire (*PHQ-9), World Health Organization Quality of Life (WHOQOL-BREF), short-form Chinese-version Problem Areas in Diabetes scale (SF-PAID-C). Answers were given on a five-point Likert scale, ranging from "strongly disagree" to "strongly agree", from "all of the time" to "none of the time", or from "extremely worried" to " not worried at all".

Randomization

Participants were alternately assigned to the intervention group or the control group, resulting in a roughly equal number of participants in the two groups and an allocation ratio of 1:1.

Clinical ethics

The study protocol was approved by the institutional review board of Chung Shan Medical University Hospital and was in compliance with the Helsinki Declaration (IRB CS12185). Written informed consent was obtained from all of the participants.

Data analysis

All statistical analyses were conducted with SPSS software, version 14.0. The data analysis set included participants who were enrolled at the beginning of the study. Dropouts and missing data due to failure to comply with the measurement protocol were excluded from final analysis. The outcomes were analyzed in the population, consisting of participants who have completed the study. Demographic data and outcome variables at baseline and follow-up visits were collected for all patients. The comparisons of variable changes from baseline to the end of study between the two groups or within the group were assessed by Student's t-test, pair-t-test or Chi-square test. All tests of intervention effects were conducted at a two-sided significance level of 0.05 unless otherwise stated.

Results

The enrollment process is shown in Figure 1. Baseline characteristics of the intervention and control groups were similar, with no significant differences in age, sex, blood pressure, HbA1c or lipid profiles (Table 1), but slight higher non-significant percentage of patients receiving insulin in intervention group. The participants' average age was 62.85 years; 52.8% were female and 50.1% has educational level of elementary school. The control of HbA1c to level of < 7% was achieved in 40% and 10% in intervention and control group, respectively, p <0.05. The control of LDL-C to level of < 100 mg/dl was increased 31.25% and 6.25% in intervention and control group, respectively, p <0.05. The control of SBP to < 130 mmHg was increased in 32.5 and 15% in intervention and control group, respectively, p <0.05. At 6 months, 30% attained 3 targets in intervention group; whereas 10% attained 3 targets in the control group (Figure 2). In addition, intervention group attenuated mean UACR level, in addition regression of macro- or microabuminuria to normoalbuminuria occurred in 31.25% and 11.25% in intervention and control group, respectively (p <0.05) (Figure 3). Table 2 shows all the changes of HbA1c, SBP, LDL-C, creatinine, UACR, behavioral and treatment changes before and after in both groups. Significant reductions in HbA1c, UACR, and carbohydrate intake per day were found in intervention group. A significant increase in SMBG and physical activity frequent per week demonstrated in intervention group. There was a significant increase in use of insulin therapy in the intervention group. In terms of quality of life and problems related to diabetes, the results are shown in Table 3.

Discussion

The pre-defined targets of HbA1c, LDL-C and SBP were achieved in a greater percentage in the intervention participants who attended the education program. In addition, the percentage of those who attained all the three targets was also greater in the intervention group. This stood in contrast to the comparison control group, whose values remained all reduced also, but in a lesser magnitude. The American Diabetes Association (ADA) recommended targets are HbA1c < 7%, LDL-C < 100 mg/dl, and SBP < 140 mmHg, known as the ABC goal [12]. To prevent diabetes complications, it is important to increase the achievement of the three targets. It is known that diabetes nephropathy can be delayed by tight simultaneous achievement of multiple ADA recommended targets [11]. To achieve the multiple

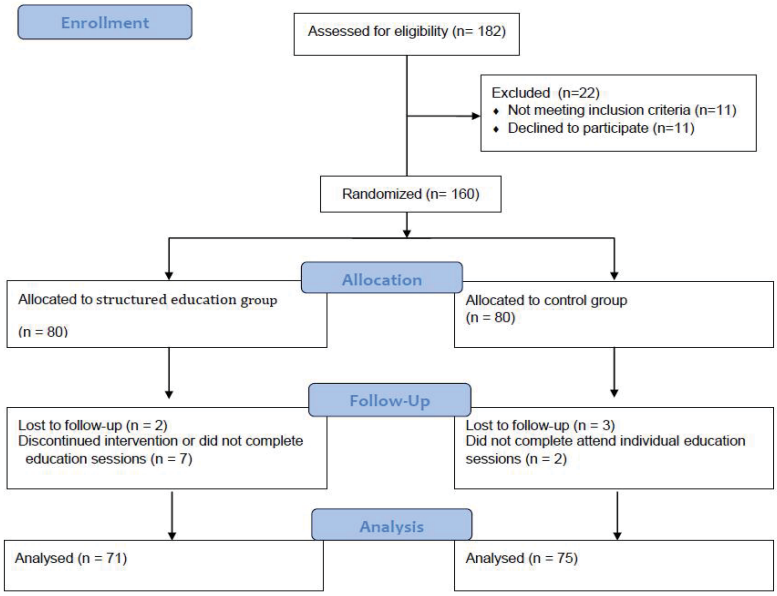

Figure 1: Allocation of participants.

Variables	Intervention group (n=71)	Control group (n=75)	P value
Age (years)	62.1 ± 9.6	63.6 ± 11.7	0.168
Female	38 (53.5)	39 (52)	0.98
Educational level Elementary school	35 (49.3)	39 (52)	0.67
Duration of diabetes (years)	12.5 ± 8.2	12.1 ± 6.3	0.73
Family history of diabetes (yes)	35 (49.3)	35 (46.6)	0.98

Footnote: HbA1c: Hemoglobin A1c; LDL-C: Low-Density Lipoprotein Cholesterol; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure. Data expressed as mean ± standard deviation, or number with percentage in parenthesis.s

Table 1: Baseline characteristics of eligible participants.

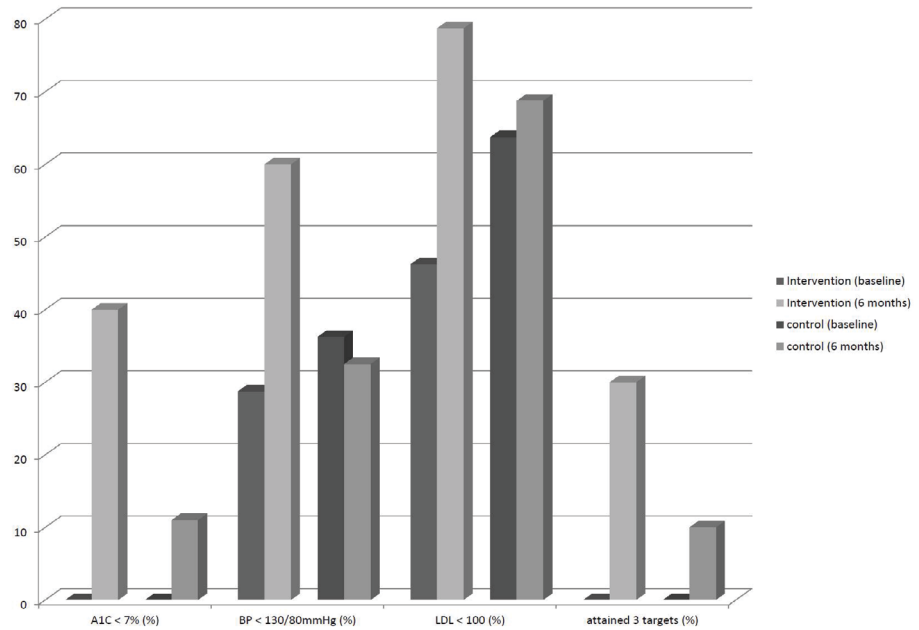

Figure 2: The percentage of control of HbA1c to level of <7%, LDL-C to level of <100 mg/dl, SBP to <130 mmHg, and the attainment of 3 targets in intervention and control group.

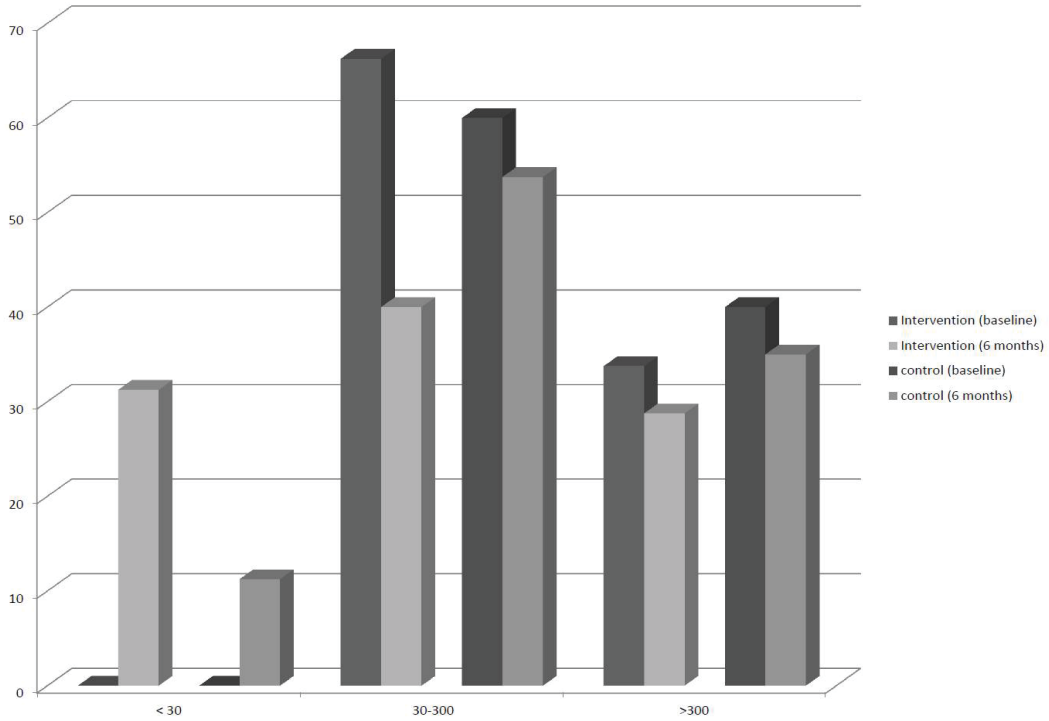

Figure 3: The percentage of changes in urine albumin creatinine ration intervention and the control group.

Variables	Intervention group (n=71)		P value[1]	Control group (n=(75)		P value[1]	P value[2]
	0 M	6 M		0 M	6 M		
SBP (mmHg)	139.6 ± 19.4	135.11 ± 18.2	0.12	142.4 ± 22.1	139.4 ± 18.5	0.37	0.13
DBP (mmHg)	76.2 ± 11.1	73.58 ± 11.6	0.14	76.1 ± 11.8	74.3 ± 13.1	0.36	0.69
LDL-C (mg/dl)	103.6 ± 28.9	85.41 ± 24.4	0.0001	102.2 ± 28.7	90.2 ± 32.4	0.01	0.29
HbA1c (%)	9.3 ± 1.1	7.9 ± 1.7	0.001	9.1 ± 0.8	8.7 ± 1.4	0.07	0.01
Creatinine (mg/dl)	1.24 ± 0.61	1.22 ± 0.91	0.81	1.22 ± 0.26	1.19 ± 0.35	0.61	0.61
eGFR (ml/min)	67.7 ± 17.7	66.23 ± 32.08	0.89	67.2 ± 13.9	66.1 ± 16.2	0.37	0.19
UACR (mg/g)	610.5 ± 122.1	486.2 ± 182.05	0.001	615.5 ± 226.2	693.08 ± 132.6	0.008	0.01
Carbohydrate intake (g/day)	253.5 ± 52.6	205 ± 53.6	0.001	265.35 ± 48.2	245.56 ± 42.1	0.006	0.01
Physical activity (times/week)	1.35 ± 1.19	3.15 ± 1.26	0.001	1.51 ± 1.15	2.16 ± 0.86	0.04	0.001
SMBG (time/week)	1.75 ± 3.34	4.75 ± 6.33	0.002	1.52 ± 4.12	2.45 ± 5.67	0.22	0.038
Oral anti-diabetic drug	35 (49.3)	30 (42)	0.66	41 (54.6)	39 (52)	0.51	0.56
Insulin therapy	36 (50.7)	41 (58)	0.66	34 (45.4)	36 (48)	0.51	0.56

Footnote: HbA1c: Hemoglobin A1c; LDL-C: Low-Density Lipoprotein Cholesterol; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; eGFR: Estimated Glomerular Filtration Rate; UACR: Urine Albumin-Creatinine Ratio; SMBG: Self-Monitoring Blood Glucose. Data expressed as mean ± standard deviation, or number with percentage in parenthesis; P value[1]: p value before and after within group; P value[2]: p value between intervention and control group.

Table 2: Metabolic parameters changes from baseline to 6 months in both groups.

Variables	Intervention group (n=71)		Control group (n=75)	
PHQ-9	6.3 ± 0.93	4.67 ± 0.76	7.35 ± 0.65	6.58 ± 0.85
SF-PAID-C	12.5 ± 0.97	10.08 ± 0.99*	11.78 ± 0.73	11.16 ± 0.9
WHOQOL-BREF				
Total score	91.15 ± 0.93	95.03 ± 0.86*	89.87 ± 0.82	91.15 ± 0.48
Physical health domain	22.98 ± 0.92	23.72 ± 0.88*	23.99 ± 0.73	24.11 ± 0.56
Psychological health domain	19.27 ± 1.00	19.84 ± 0.89	18.27 ± 0.79	18.44 ± 0.97
Social relationships domain	13.54 ± 0.89	13.71 ± 0.82	14.35 ± 0.95	14.56 ± 0.59
Environmental health domain	30.42 ± 0.85	31.54 ± 0.81*	29.85 ± 0.78	30.75 ± 0.81

Footnote: PHQ-9: Patient Health Questionnaire; SF-PAID-C: Short-Form Chinese-Version Problem Areas in Diabetes scale; WHOQOL-BREF: WHO Quality of Life-BREF; *p<0.05 within group. Data expressed in mean ± standard deviation.

Table 3: Quality of life and problems changes from baseline to 6 months in both groups.

targets is in particular a challenge in clinical practice. A recent large meta-analysis found that lifestyle interventions reduced HbA1c by 0.37%, with <1-mmHg changes in both SBP and diastolic blood pressure, but no difference was found in either LDL cholesterol or high-density lipoprotein cholesterol [13]. Some barriers commonly identified by physicians or patients in achieving enduring multiple treatment goals in diabetes complex management, which include non-compliance with exercise and/or diet, non-adherence with medication regimen, polypharmacy and many others. Education programs showed promising results that could improve their self-care behavior adherence. As reported in a previously sub-optimally controlled type 2 diabetic patients, greater improvements in glycemic control and self-care ability goals in those who underwent the Diabetes Conversation Map™ structured education program compared with those who received usual care [14]. The significant improvement in the achievement of guidelines treatment goals recognized in this study might be, somewhat are related to the educational component of this study. The general knowledge about diabetes kidney disease or CKD and its risk factors is low [15]. The majority kidney disease education studies are purposed to improve patient's involvement in the selection of kidney replacement therapies for ESRD as well as engagement of eligible patients for kidney transplant evaluation. A Taiwan's study found that the incidence of dialysis in those who received usual care was 43%, but in the intervention group who received multidisciplinary comprehensive educational sessions covering conventional kidney disease care themes in individual teaching sessions provided by professional health workers, the dialysis incidence was 14% [16]. Another structured care group demonstrated to have 3 times more likely than usual care to attain 3 treatment targets and reduced the renal end points in type 2 diabetes [17]. The percentage of three goal achievement over the study period in those who received usual care was 10% and in comparison was 30% in the intervention group. Was similar to those who had enhance or reinforced on these targets.

There is less programs targeting those with high risk for development of kidney diseases, such as diabetes. It has long been recognized that general awareness about chronic kidney disease, particularly among those in early stage, is poor [18]. Therefore, we selected patients with early stage of diabetes kidney disease to deliver the education program, in an effort to improve awareness of diabetic kidney disease and to early prevention of further decline in renal function.

Education contributes to health through enhanced health knowledge, improve coping and problem-solving skills. Therefore, allows patients to engage in health behaviors, self-manage their medical circumstances, and make better decisions about their health status. Higher levels of education are more likely to have less chronic disease, and lower educational achievement was associated with reduced kidney function and increased mortality [19,20]. The study included 50% of participants who had only an elementary school level education indicating that education program provided in the study was possible achieved even in those with lower educational attainment. However, it is important to recognized that even those with higher educational attainment may have low health-related knowledge, because do not necessary correlate with health self-care behavior skills achieved.

The study has several limitations. First, we did not examine the medication adherence. However, we have recorded the treatment changes throughout the study period. The changes were similar in both groups. Second, we did not have a treatment protocol to follow, however, all the participants were under their routine clinic visits in endocrinologist or nephrologist, in addition, in Taiwan, there was a diabetes shared care program and CKD-integrated care program, which standardized the clinical practice. We analyzed those who have complete follow-up and completed the sessions. Though randomized, the participants who attended or had completed the education sessions were thought to be more motivated for behavioral changes. This pilot study was feasible and statistically significant differences may be determinable in future studies. Future studies required careful design to overcome this problem, including intention-to treat analysis.

Conclusion

In conclusion, type 2 diabetes with early diabetes kidney disease receiving a structure education program delivered by diabetes educator team were more likely to attain multiple treatment targets, by accepting treatment changes, and improved their self-care behaviors.

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