Effect of the nurse-led program on blood glucose control and microalbuminuria development in type 2 diabetic populations

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Abstract

Current study was to evaluate whether the nurse-led program can improve glycated hemoglobin (HbA1c) control and reduce the incidence of microalbuminuria in type 2 diabetic mellitus (DM2) populations. A total of 150 DM2 subjects were randomly assigned to the usual-care group and nurse-led program group. Study endpoints included the HbA1c value, the percentage of subjects with HbA1c < 7.0%, the incidence of microalbuminuria, and the rate of adhering to antidiabetic drug at 6 months' follow-up. At baseline, there was no difference in fasting plasma glucose, HbA1c, proportion of subjects with HbA1c < 7.0%, the use of antidiabetic drug, and urinary albumin-creatinine ratio between these two groups. After 6 months' follow-up, the mean fasting plasma glucose and HbA1c were lower in the nurse-led program group, as was the proportion of subjects with HbA1c < 7.0%. The median urinary albumin-creatinine ratio and rate of incident microalbuminuria were also lower in the nurse-led program. The nurse-led program was associated with higher odds of achieving HbA1c < 7.0% and a lower incidence of microalbuminuria. After adjusted for covariates, the nurse-led program was still associated with 32% higher odds of achieving HbA1c < 7.0% and 11% lower incidence of microalbuminuria. These benefits were consistent by sex and age, while greater in those with obesity or hypertension (*P* interaction < .05). The nurse-led program is beneficial for blood glucose control and prevention of microalbuminuria.

Abbreviations: DM2 = type 2 diabetic mellitus, FPG = fasting plasma glucose, HbA1c = glycated hemoglobin, uACR = urinary albumin-creatinine ratio.

Keywords: albuminuria, blood glucose, diabetes mellitus

1. Introduction

Type 2 diabetes mellitus (DM2) is associated with substantial morbidity and mortality.[1,2] The epidemiological studies have shown that the prevalence and incidence of DM2 has been continuously increasing in China and worldwide.[2,3] Progress in the management of DM2 has been made in recent decades. Nevertheless, a substantial proportion of people still develop diabetes-related complications, such as diabetic nephropathy.[4,5] Therefore, improvement in blood glucose control for DM2 subjects is important to prevent these complications.

Professional nurses play important roles in the management of chronic disease. For example, prior studies have demonstrated that among patients with chronic heart failure, compared to the usual-care, the nurse-led program was associated with improvement in quality of life, mental health status, adherence to medication therapy and heart failure management.[6,7] DM2 is a chronic disease which requires lifestyle modification, health education, regular blood glucose monitoring and adherence to medication therapy among others.[8] Findings from prior studies have shown that the nurse-led program can help improve blood glucose control.[9–11] Nevertheless, these data were mostly from developed countries. Little is known about whether the nurse-led program can be applied to the DM2 subjects in China, considering the substantial differences in sociodemographic between the developed countries and China. In addition, whether the nurse-led program can help reduce the incidence of diabetes-related complication is also unknown.

Herein, we enrolled individuals with DM2 diagnosis of less than 1 year, and conducted a randomized, parallel, open-label study to evaluate whether the nurse-led program can improve glycated hemoglobin (HbA1c) control and reduce the incidence of microalbuminuria in DM2 Chinese subjects.

2. Methods

2.1. Study design and participants

This was a randomized, parallel, and open-label study. The current study was approved by the Clinical Research Ethic Committee of Hainan Western Central Hospital. Detailed

information of the current study was provided to participants before written informed consent was obtained. The inclusion criteria were as follows: ≥18 years old; DM2 was based on prior physician diagnosis plus current treatment with antidiabetic medication; time since diagnosis of DM2 ≤ 1 year. The exclusion criteria were as follows: documented diagnosis of type 1 diabetes; diagnosis of microalbuminuria or macroalbuminuria at baseline; other diabetes-related micro- or macro-complication; previous diagnosis of cardiovascular disease which included physician diagnosis of coronary heart disease, myocardial infarction, ischemic stroke, peripheral arterial disease, heart failure and atrial fibrillation; diabetic ketoacidosis or hyperosmolar hyperglycemic non-kenotic syndrome in the last 6 months. Study flowchart was shown in the Figure 1.

2.2. The usual-care and the nurse-led program

In the current study, 150 participants were enrolled by physicians in our hospital from June of 2020 to June of 2021, and they were randomly assigned to either the usual-care group or the nurse-led program group for 6 months. The method used to randomize participants have been described in our prior study.[12] In brief, patients with odd digit were assigned into the usual-care group and those with even digit were assigned into the nurse-led program group. In the usual-care group, face-to-face consultation on self-care management, lifestyle modification, and importance of medication adherence was provided by register nurses at baseline. In the nurse-led program group, which was conducted by the nurses, in addition to the usual-care, patients would receive a detailed information booklet, which includes information on how to conduct self-care management and lifestyle modification; 10-minute movie clips about the importance of adhering to medication therapy; attended four weekly group-based educational sessions which included the contents as follows: the importance of low-carbohydrate diet, regular physical exercise, self-monitoring blood glucose and any diabetes-related symptoms, potential side effects related to medications, and hypoglycemic symptom; and received follow-up telephone interview every two weeks by register nurses.

2.3. Data collection

Demographics, anthropometrics, comorbid conditions, and current medication therapy were collected during personal interview by two investigators. Obesity was defined as body mass index ≥28 kg/m^2 according to the China's criterion.[13] Fasting venous blood with at least 8 hours fasting was drawn to evaluate fasting plasma glucose (FPG), HbA1c, lipid profiles and creatinine level at baseline and at 6 months follow-up. All the measurements were performed using liquid chromatography with Beckman Coulter in our central laboratory. Smoking status was defined as using cigarette in the recent one month; hypertension was based on physician diagnosis and/or antihypertensive drugs; dyslipidemia was based on physician diagnosis and/or usage of statins; medications usage in terms of antiplatelets, antihypertensives, antidiabetics and statins were based on self-report. Estimated glomerular filtration rate was calculated using the Modification of Diet in Renal Disease formula.[14] In addition, 24 hours urine at baseline and at 6 months' follow-up were collected for the assessment of urinary albumin-creatinine ratio (uACR), with uACR < 30 mg/g was defined as normal, 30 to 300 mg/g microalbuminuria and >300 mg/g macroalbuminuria.[15] All the measurements were performed in the core laboratory of our hospital. Antidiabetic drug at baseline and follow-up was collected to assess the adherence to medication therapy.

2.4. Study endpoints

Study endpoints of the current study included the value of HbA1c at follow-up, and the percentage of patients with HbA1c < 7% at follow-up. In addition, we also compared the incidence of microalbuminuria and the rate of adhering to antidiabetic drug at follow-up between these two groups.
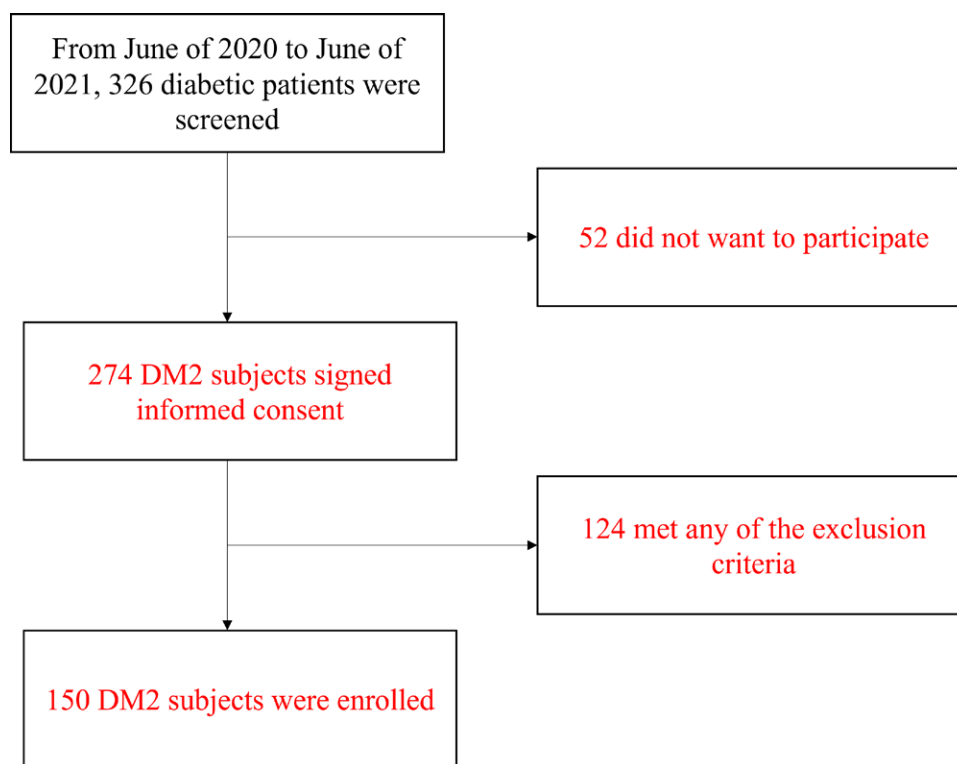

Figure 1. Study flowchart.

2.5. Statistical analysis

Continuous variables with a normal distribution were presented as mean and standard deviation, otherwise were presented as median (interquartile range). Categorical variables were presented as number and percentage. Continuous variables were compared using the Student t test if normal distribution, otherwise were compared using the Mann–Whitney U test. Categorical variables were compared using the χ^2-test. To assess the relationship between the nurse-led program and study endpoints, multivariable cox proportional regression analysis was performed. The hazard ratio (and its 95% confidence interval were reported. A subgroup analysis was also performed. All analyses were carried out using the SPSS Statistics version 23.0, IBM Company (Chicago, IL), and a two-sided P value < .05 was considered statistically significant.

3. Results

3.1. Baseline characteristics

As shown in Table 1, there was no difference in baseline characteristics between the usual-care group and the nurse-led program group. The median duration of diabetes in both groups was 6.8 and 7.0 months. The mean age was 51.5 and 50.7 years, and males were 58.1% and 57.9%, respectively. The mean body mass index was 26.3 and 26.5 kg/m², with a prevalence of obesity was 43.2% and 44.7%, respectively. Approximately one-third of study participants were current smokers, 70% had hypertension and more than half had dyslipidemia in both groups. The mean estimated glomerular filtration rate was 83.8 mL/min/1.73 m² and 83.8 mL/min/1.73 m² in both groups. The use of medication was comparable at baseline between these two groups.

3.2. Study endpoints

As presented in Table 2, at baseline, there was no difference in FPG, HbA1c, proportion of participants with HbA1c < 7.0%, the use of antidiabetic drug and uACR between these two groups. After 6 months' follow-up, compared to the usual-care group, the mean FPG and HbA1c were lower in the nurse-led program group, as was the proportion of participants

with HbA1c < 7.0%. In addition, the median uACR and rate of incident microalbuminuria was also lower in the nurse-led program.

3.3. Association between the nurse-led program and study endpoints

As shown in Table 3, the nurse-led program was associated with higher odds of achieving HbA1c < 7.0% and a lower incidence of microalbuminuria. After adjusted for covariates, the nurse-led program was still associated with 32% higher odds of achieving HbA1c < 7.0% and 11% lower incidence of microalbuminuria.

3.4. Subgroup analysis

As presented in Table 4, the nurse-led program was associated with higher odds of achieving HbA1c < 7.0%, which was consistent by sex and age. Notably, these benefits were greater in those

Table 2
Study endpoint.

	Usual-care (n = 74)	Nurse-led program (n = 76)
At baseline		
FPG (mmol/L)	7.1 ± 1.3	7.0 ± 1.4
HbA1c (%)	6.8 ± 1.0	6.8 ± 1.1
HbA1c < 7.0%, n (%)	45 (60.8)	46 (60.5)
Antidiabetic drug, n (%)	74 (100)	76 (100)
uACR (mg/g)	15.6 (6.8–22.3)	16.4 (7.0–21.9)
At 6 mo' follow-up		
FPG (mmol/L)	7.2 ± 1.2	6.6 ± 1.1*
HbA1c (%)	6.9 ± 1.0	6.4 ± 1.1*
HbA1c < 7.0%, n (%)	44 (59.5)	50 (65.8)*
Antidiabetic drug, n (%)	71 (95.9)	76 (100)
uACR (mg/g)	22.3 (11.5–28.2)	17.2 (9.3–25.4)*
Microalbuminuria, n (%)	7 (9.5)	2 (2.6)*

FPG = fasting plasma glucose, HbA1c = glycated hemoglobin A1c, uACR = urine albumin creatinine ratio.

*P < .05 versus the usual-care group.

Table 1
Baseline characteristics.

Variables	Usual-care (n = 74)	Nurse-led program (n = 76)	P value
Duration of diabetes (mo)	6.8 (3.2–10.9)	7.0 (3.4–11.2)	.12
Age (yr)	51.5 ± 10.9	50.7 ± 9.4	.27
Male, n (%)	43 (58.1)	44 (57.9)	.33
Education ≥ High school, n (%)	43 (58.1)	45 (59.2)	.19
Systolic blood pressure (mm Hg)	132 ± 13	133 ± 13	.68
Diastolic blood pressure (mm Hg)	80 ± 10	80 ± 11	.84
Heart rate (beat per min)	74 ± 17	75 ± 16	.46
Body mass index (kg/m²)	26.3 ± 5.2	26.5 ± 5.4	.70
Obesity, n (%)	32 (43.2)	34 (44.7)	.52
Smoking, n (%)	25 (33.8)	27 (35.5)	.37
Hypertension, n (%)	52 (70.3)	53 (69.7)	.21
Dyslipidemia, n (%)	43 (58.1)	43 (56.6)	.90
Creatinine (μmol/L)	72.5 ± 18.5	73.1 ± 19.4	.84
eGFR (mL/min/1.73 m²)	83.8 ± 14.3	84.2 ± 15.2	.69
LDL-cholesterol (mmol/L)	3.0 ± 0.9	3.1 ± 1.0	.58
Total cholesterol (mmol/L)	4.9 ± 0.8	5.0 ± 0.8	.92
Triglyceride (mmol/L)	1.6 (0.7–2.9)	1.7 (0.7–3.0)	.55
HDL-cholesterol (mmol/L)	1.10 ± 0.04	1.07 ± 0.05	.64
Antiplatelet, n (%)	14 (18.9)	15 (19.7)	.73
Antihypertensive, n (%)	45 (60.8)	45 (59.2)	.36
Statins, n (%)	37 (50.0)	39 (51.3)	.28

eGFR = estimated glomerular filtration rate, HDL = high density lipoprotein, LDL = low density lipoprotein.

Association between the nurse-led program and study endpoints.

	Hazard ratio (95% confidence interval)			
	Unadjusted	***P* value**	**Adjusted**	***P* value**
HbA1c < 7.0%	1.65 (1.38–1.91)	.008	1.32 (1.16–1.62)	.01
Microalbuminuria	0.82 (0.70–0.90)	.01	0.89 (0.77–0.98)	.03

Adjusted for age, sex, systolic blood pressure, body mass index, estimated glomerular filtration rate, antihypertensive and statins therapy.
HbA1c = glycated hemoglobin A1c.

Subgroup analysis.

	Hazard ratio (95% confidence interval)	*P* interaction
HbA1c < 7.0%		
Men	1.22 (1.09–1.45)	.15
Women	1.18 (1.06–1.36)	
Age < 50 yr	1.30 (1.14–1.42)	.24
Age ≥ 50yr	1.23 (1.12–1.37)	
Obese	1.42 (1.27–1.55)	.02
Non-obese	1.16 (1.01–1.25)	
Hypertension	1.39 (1.23–1.50)	.01
Non-hypertension	1.13 (1.02–1.22)	
Microalbuminuria		
Men	0.86 (0.78–0.95)	.30
Women	0.90 (0.80–0.97)	
Age < 50 yr	0.89 (0.79–0.94)	.45
Age ≥ 50 yr	0.86 (0.81–0.96)	
Obese	0.75 (0.69–0.84)	.009
Non-obese	0.85 (0.80–0.99)	
Hypertension	0.72 (0.66–0.85)	.03
Non-hypertension	0.86 (0.79–0.98)	

HbA1c = glycated hemoglobin A1c.

with obesity or hypertension (*P* interaction < .05). Similarly, the benefits of reducing the incidence of microalbuminuria were consistent by sex and age, and these benefits were greater in those with obesity or hypertension (*P* interaction < .05).

4. Discussion

To our knowledge, this should be the first few studies to evaluate the influences of the nurse-led program for the management of type 2 diabetic patients from China. There are some important findings of the current study. First, compared to the usual-care, the nurse-led program was beneficial for the blood glucose control, as reflected by the PFG, HbA1c, and the proportion of participants with HbA1c < 7.0% at 6 months' follow-up. Second, the median uACR and rate of incident microalbuminuria were lower in the nurse-led program group. Third, these benefits were consistent in both sexes and young and older participants, while those were greater in participants with obesity or hypertension. These findings demonstrate that the nurse-led program is a feasible approach for improving the quality of healthcare for type 2 diabetic patients from China. We believe that findings of the current study could provide novel insights into better understanding the role of the nurse-led program for the care of diabetic patients from China.

With the lifestyle change, the prevalence and incidence of diabetes have been continuously increasing in China. Notably, diabetes is associated with substantial cardiovascular and renal morbidity and mortality. Improvement in diabetes management is essential to reduce these complications.[16,17] Besides physicians, professional nurses have also made

significant contributions to the management of chronic diseases, such as chronic heart failure. Indeed, our recent studies have demonstrated that the nurse-led program is beneficial for improving the quality of healthcare and outcome for patients with chronic heart failure.[6,7] Leveraging on these experiences, we investigated whether the nurse-led program can also improve the control of diabetes and reduce the incidence of microalbuminuria.

Consistent with prior reports from other population groups,[9–11] we found that compared to the usual-care group, six months of the nurse-led program intervention was associated with improvement in blood glucose control. There are four important reasons to explain these benefits. First, in the nurse-led program, a detailed information booklet, which included information on how to conduct self-care management and lifestyle modification, was provided to the patients. This information can help patients to improve their lifestyle, which in turn facilitated blood glucose control. Second, 10-minute movie clips about the importance of adhering to medication therapy was provided, which helped to increase adherence to antidiabetic drug. Indeed, as shown in Table 2, after 6 months' follow-up, all patients in the nurse-led program remained on antidiabetic therapy. Third, patients in the nurse-led program attended weekly group-based educational sessions, which provided a unique opportunity to educate diabetic patients. Last but not the least, follow-up telephone interview was also provided every two weeks, during which the nurses can provide timely feedback to the patients.

Our current study was featured by the advantages that the results show that the nurse-led program was not only associated with improvement in blood glucose control, but also was associated with reduced incidence of microalbuminuria, which is an early marker of diabetic nephropathy,[18] which have not been evaluated in prior studies.[9–11] This finding has important clinical implication as diabetes is an important risk factor of end stage renal disease, which is associated with substantial health and economic loss.[19–21] Preventing microalbuminuria development with the nurse-led program intervention can help reduce the risk of end stage renal disease in a cost-effective way. Further studies are needed to corroborate our preliminary results.

We further explored whether these benefits differed according to demographics and comorbid conditions. Notably, the results suggest that the benefits of the nurse-led program intervention were consistent regardless of sex and age, demonstrating the robustness of the current findings. Interestingly and importantly, we found that the benefits were greater in those with obesity or hypertension. These results suggest that the nurse-led program had greater benefits for high-risk diabetic patients. The major differences between the current study and prior reports were that we applied the booklet for diabetic cares and all the performances were guided by the nurses. On the other hand, prior studies did not reveal diabetes-related complications, while in this study we also evaluated the microalbuminuria, suggesting that the improvement in diabetes can prevent its associated complications.

There are some limitations of our current study. First, this was a single center study and future multicenter studies are needed to confirm our current findings. Second, the sample size was relatively small which might limit the statistical power to identify potential differences between two groups. Third, participants of current study were newly diagnosed diabetes and whether these benefits can be applied to those with long-term DM2 are unknown. Fourth, the duration of the nurse-led program was 6 months and whether this program can be sustainable for a longer duration was unknown. Last but not the least, in this study we were unable to evaluate the cost-effectiveness of the nurse-led program which should be further evaluated in the future.

5. Conclusion

In conclusion, our current study shows that the nurse-led program is beneficial for blood glucose control and prevention of microalbuminuria. Further studies are needed to confirm our current findings and also to evaluate whether the nurse-led program can prevent other diabetic complications such as cardiovascular disease.

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