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ORIGINAL RESEARCH

A Prospective Cohort Study on the Management of Young Patients with Newly Diagnosed Type 2 Diabetes Using Mobile Medical Applications

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ABSTRACT

Introduction: The aim of this study was to evaluate the effect of using a mobile medical application (app) for self-monitoring of blood glucose (SMBG) and blood glucose control in young patients with newly diagnosed type 2 diabetes mellitus (T2DM).

Methods: This was a prospective cohort study involving young patients with newly diagnosed T2DM. On a voluntary basis, the patients chose to be included in a group in which they were followed up for 24 weeks with a mobile medical app and the changes in laboratory data and frequency of SMBG observed via the app, or in a group in which they received traditional medical treatment and follow-up. The results between the two groups were compared.

Results: A total of 126 patients signed the informed consent form and were enrolled in the study, of whom 66 chose the mobile medical group, which used the mobile medical app, and the remaining 60 patients chose the traditional medical treatment model. The differences in the physical and chemical indicators between the app-using group and the traditional medical model group were not statistically significant at baseline ($p > 0.05$). At 24 weeks of treatment, the levels of glycosylated hemoglobin A1c (HbA1c), total cholesterol, triglycerides, and low-density lipoprotein cholesterol were significantly reduced in all patients compared to before treatment ($p < 0.05$). The app-using group had a higher HbA1c compliance rate and higher frequency of both SMBG and doctor–patient communication than the traditional medical model group ($p < 0.01$). The HbA1c compliance rate of patients using the mobile medical app was 1.53-fold higher than that of the traditional medical model group. At 24 weeks, HbA1c was negatively correlated with the frequency of SMBG ($r = -0.208$, $p = 0.020$) and the frequency of doctor–patient communication ($r = -0.323$, $p = 0.000$). Additionally, there was a positive correlation between the frequency of SMBG and doctor–patient communication ($r = 0.579$, $p = 0.000$).

Conclusion: A mobile medical app is helpful to young patients with newly diagnosed T2DM for monitoring their blood glucose level and improving their blood glucose control to meet the standard.

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INTRODUCTION

The prevalence of type 2 diabetes mellitus (T2DM) in China is rapidly increasing, with the latest Chinese T2DM epidemiological study data indicating a diabetes prevalence of 10.4% among adult Chinese. The prevalence of diabetes in economically developed areas is significantly higher than that in underdeveloped areas, and the prevalence in urban areas is higher than that in rural areas (12.0 vs. 8.9%) [1]. If a glycosylated hemoglobin A1c (HbA1c) level of $\geq$ 6.5% is added to the diagnostic criteria, the prevalence of diabetes in Chinese adults rises to as high as 11.6%) [1]. The prevalence of newly diagnosed diabetes is 8.1% [1]. Among all T2DM patients, 25.8% are receiving treatment, of whom only 39.7% have good blood glucose control [2].

The economic burden of T2DM and its chronic complications are increasing year by year in China. Blood glucose control can reduce the risk of diabetic complications and delay the progression of complications. The complicated pathogenesis of T2DM has to date defeated all attempts at achieving a radical cure for this disease, which means that patients need to receive systematic and long-term treatment. A patient's diabetes education and early glycemic control can have a great impact on the patient's long-term self-management.

With the development of the Internet, health and medical information are now more easily available. However, people with chronic diseases, such as T2DM, need more than just hand-held Internet information; rather, there is a need for a deeper knowledge that will facilitate direct communication with doctors and provide the scientific basis for self-management. A mobile medical application (app) is a medical application software based on mobile terminals, such as mobile phones. Some apps have functions that can provide the patient with the possibility to systematically self-manage a chronic disease over the long term, such as integrated health information, patient education, doctor–patient communication, health data records, lifestyle reminders, among many more [3, 4].

To evaluate the effectiveness of such medical apps for the self-management of diabetic patients, in this study we used a mobile phone diabetic management app as a medium to observe the self-monitoring of blood glucose (SMBG) and changes in health parameters of young patients with newly diagnosed T2DM. We then compared the data with data obtained from patients receiving traditional medical treatment.

METHODS

Patient Eligibility and Study Design

From 1 January 2018 to 31 May 2018, eligible patients with diabetes admitted to the endocrinology clinic of Beijing Friendship Hospital were enrolled in the study. Patients were eligible for entry in the study when: (1) the diagnostic criteria of T2DM were met, and the duration of disease was < 6 months; (2) patient age ranged between 18 and 40 years; (3) the patient showed clear consciousness and comprehension; (4) the patient volunteered freely to participate; (5) there was no history of oral hypoglycemic drugs or use of an insulin app. The exclusion criteria were: (1) type 1 DM, gestational diabetes mellitus, and other special types of diabetes; (2) alanine aminotransferase (ALT) level of more than twofold the upper limit of normal; (3) serum creatinine (Cr) level of higher than the upper limit of normal; (4) mobility difficulties, unclear consciousness, or unable to communicate properly; (5) no access to household blood glucose meter or blood glucose test strip. The exit criteria were: (1) over 5 weeks loss to follow-up; (2) no SMBG data for > 5 weeks

On a voluntary basis, the subjects chose to be included in either the traditional medical group or the mobile medical group (app-using group). In the traditional medical group, the patient was required to visit the outpatient department every 4 weeks. At each visit, the doctor communicated with the patient, assessed the patient's medical condition, and adjusted the disease management plan if/as needed. Those in the mobile medical group used the medical app

as an aid to assist in doctor–patient communication, to evaluate the patient's condition and to adjust the therapeutic schedule.

This study complied with the principles of medical ethics and quality management practices for effective research (approved by the ethics committee of Beijing Friendship Hospital, 2018-P2-016-01). All procedures performed in studies involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments. All patients signed informed consent forms prior to entry into the study.

Methods

Target Mobile Medical Apps

A diabetes management app that had both doctor and patient versions was selected. The patient's version had the features of promoting diabetes knowledge and health information, recording health data, reminding the patient on the need for blood glucose measurement, providing the platform for doctor–patient communication, and many more. The doctor's version had the features of checking patients' open data, recording blood glucose values and related changes in curves, setting blood glucose targets, making appointments for patient education via the telephone, providing the platform for doctor–patient communication, among others.

On the day of enrollment, the doctor used the doctor's version app to generate a quick response (QR) code business card. The patients in the app-using group scanned this QR code provided by the doctor and downloaded the patient's version of the app; they were immediately linked with the doctor's account. Patients provided their own basic health information truthfully and uploaded this information by mobile phone. The patients in the traditional medical group also provided personal health information during an appointment, which was recorded by the doctor. Based on the "Guideline for the prevention and treatment of type 2 diabetes in China (2017 edition)," doctors set blood glucose control targets for all patients, formulated blood sugar

control programs, explained SMBG methods, and suggested that patients should perform SMBG at least once a week. All patients were given the diabetic education curriculum (once every 4 weeks), and journals in which to record blood glucose levels were distributed to the traditional medical group patients.

Thereafter, patients in the app-using group were advised to use other functions of the app software, such as acquiring knowledge about diabetes, formulating diet and exercise goals, and contacting and consulting the doctor through the software. The doctor logged into the app once a week to respond to a patient's questions, evaluate the patient's blood glucose records, and supervise patients who did not upload blood glucose records. In the traditional medical group, patients could make follow-up visits every 4 weeks according to the traditional medical model, and at least one blood glucose record would be provided. The doctor was responsible for making the appointment for the next visit but did not take the initiative to contact the patient on any non-review date.

General Clinical Data

Gender, age, and disease course were obtained from all patients. All patients were measured for height and weight using the same measurement tool at the time of enrollment and at 24 weeks after enrollment, and the body mass index was calculated.

Laboratory Examinations

Blood biochemistry was measured at the Beijing Friendship Hospital Clinical Laboratory Center at the time of enrollment and at 24 weeks after enrollment, including fasting plasma glucose, total cholesterol (TC), triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), ALT, and Cr. HbA1c was also determined at the same time.

Definition of Evaluation Indicators

The target HbA1c was < 7.0%. After follow-up of 24 weeks, those patients whose HbA1c was < 7.0%, were considered to have reached the standard.

The frequency of communication between doctors and patients was recorded as "times per week." Patients sent messages to their doctors through the mobile app, went to the outpatient clinic for treatment, or participated in diabetes education courses; each of these was recorded as one doctor–patient communication, and only recorded once a day.

The number of times that the blood glucose was uploaded by the app-using group's patients via the mobile phone and the number of times that the traditional medical group provided written records were recorded as "times per week."

Statistical Processing

The SPSS version 20.0 software package (IBM Corp., Armonk, NY, USA) was used for statistical analysis. The measurement data of the normal distribution were expressed as the mean ± standard deviation and the data of the skewed distribution were expressed as the median with the interquartile range. Count data were expressed as frequency and percentage. For the comparison between groups, an independent sample t test was used for the normal distribution of variables, and the Mann–Whitney U test was used for the skewed distribution. The paired sample t test was applied to the normal distribution variable in the group, and the Wilcoxon rank-sum test was applied to the skewed distribution. The rate was compared using the Chi-square test. The Pearson test was used to analyze the inter-variable correlation. Significance was achieved when a p value was < 0.05.

RESULTS

A total of 126 patients (65 males, 61 females) who met the inclusion criteria of the study volunteered to participate in the trial and provided informed consent. Of these, 66 volunteers (41 males, 25 females; average age $32.20 ± 6.10$ years) chose the mobile medical group (app-using group), and 60 (24 males, 36 females; average age of $33.22 ± 5.28$ years) declined to be part of the mobile medical group and instead chose the traditional medical

model (traditional medical group). The reasons among the latter patients for not choosing the mobile medical group were "too much trouble" (34 cases) and "for fear of privacy leakage" (17 cases); nine patients did not disclose their reasons for their choice.

There was no significant difference in the clinical and demographic data between the traditional medical group and the mobile medical group (app-using group) at baseline (Table 1).

At 24 weeks of treatment, the HbA1c, TC, TG, and LDL-C levels in the two groups were significantly lower than the respective baseline values. Those in the mobile medical group (app-using group) had a significantly higher HbA1c compliance rate, frequency of SMBG, and frequency of doctor–patient communication than those in the traditional medical group (Table 2).

At 24 weeks, the HbA1c level was negatively correlated with the frequency of SMBG and the frequency of doctor–patient communication. In addition, there was a positive correlation between the frequency of SMBG and the frequency of doctor–patient communication frequency (Table 3).

DISCUSSION

The current prevalence of T2DM in China does not paint an optimistic picture, especially among the younger generation of the population, and the prevalence rate is increasing annually. Young people are under high work pressure and live fast-paced lives and thus are seemingly insufficiently aware of the risk of diabetes. The behavioral characteristics of this group, such as their dietary habits and daily schedules, are highly variable. This life-style results in poor adherence and a low blood glucose compliance rate in young T2DM patients [5]. However, young people are the main adherents to the use of mobile apps and have a higher degree of acceptance and a stronger ability to operate and learn how to use new apps. Therefore, we selected young T2DM patients as our study subjects for observation and analysis.

Table 1 Comparison of patient characteristics at baseline according to treatment group

Group	Mobile medical group	Traditional medical group	p
Case (n)	66	60	
Age (years)	32.20 ± 6.10	33.22 ± 5.28	0.320
Gender (male/female)	41/25	24/36	
Course of T2DM (years)	1 (0.10–3.00)	2 (0.52–4.75)	0.054
Smoking history (years)	3 (0.10–7.30)	2.2 (0.10-6.70)	0.092
Drinking history (years)	3.5 (0.2–7.10)	2.7 (0.10–5.00)	0.087
Complications (n)			
Hypertension	9	6	
Hyperlipidemia	21	29	
Fatty liver	47	42	
Hyperuricemia	7	6	
Family history of diabetes	24	29	
BMI (kg/m^2)	26.27 ± 4.64	25.52 ± 4.76	0.375
ALT (U/L)	21 (16–43)	17.5 (14–26.5)	0.073
Cr (μmol/L)	68.71 ± 14.59	70.02 ± 10.54	0.567
TC (mmol/L)	4.70 ± 0.93	4.91 ± 1.04	0.236
TG (mmol/L)	1.71 (1.06–2.99)	1.30 (1.04–2.47)	0.297
LDL-C (mmol/L)	2.71 ± 0.68	2.78 ± 0.72	0.570
HbA1c (%)	9.82 ± 2.47	9.05 ± 2.32	0.077

Measurement data with a normal distribution are expressed as the mean ± standard deviation (SD); measurement data with a skewed distribution are expressed as the median with the interquartile range (IQR) in parenthesis

$p < 0.05$ indicates a statistically significant difference between treatment groups

T2DM Type 2 diabetes mellitus, *BMI* body mass index, *ALT* alanine aminotransferase, *Cr* creatinine, *TC* total cholesterol, *TG* triglycerides, *LDL-C* low-density lipoprotein cholesterol, *HbA1c* glycosylated hemoglobin

A meta-analysis of five large clinical studies (33,040 patients), namely, the United Kingdom Prospective Diabetes Study (UKPDS), the Prospective Pioglitazone Clinical Trial in Macrovascular Events (PRO active), Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE), the VA Diabetes Trial (VADT), and Action to Control Cardiovascular Risk in Diabetes (ACCORD), showed that intensive control of glucose resulted in a 0.9% reduction in HbA1c, a 17% reduction in the risk of non-fatal myocardial infarction, a 15% reduction in coronary heart disease risk, and a 7% reduction in stroke risk [6]. Therefore, in our study we selected the HbA1c compliance rate as the main assessment index of the hypoglycemic effect. Our results show that all patients had improved HbA1c after 24 weeks. The HbA1c compliance rate of the app-using group was better than that of the traditional medical group, a finding which is consistent with the results of relevant studies by researchers from many countries [7]. Marcolino et al. [8]

Table 2 Comparison of data at 24 weeks according to treatment group

Group	Mobile medical group	Traditional medical group
Case (n)	66	60
BMI (kg/m^2)	25.68 ± 4.21	25.48 ± 4.65
ALT (U/L)	20.50 (12.75–28.25)##	18.50 (13.00–28.00)
Cr (μmol/L)	71.55 ± 11.45	67.45 ± 9.04
TC (mmol/L)	4.50 ± 0.52#	4.53 ± 0.72#
TG (mmol/L)	1.45 (1.10–2.15)##	1.46 (1.07–1.91)##
LDL-C (mmol/L)	2.42 ± 0.36##	2.49 ± 0.54##
HbA1c (%)	6.76 ± 0.50##,**	7.25 ± 0.98##
HbA1c compliance rate (%)	71.21**	46.67
SMBG frequency (times per week)	2.47 ± 0.90**	1.27 ± 0.46
Doctor–patient communication frequency (times per week)	1.53 ± 0.33**	0.38 ± 0.09

Measurement data with a normal distribution are expressed as the mean ± SD; measurement data with a skewed distribution are expressed as the median with the IQR in parenthesis

SMBG Self-monitoring blood glucose

#, ## Significant difference compared with the intragroup baseline at $p < 0.05$ and $p < 0.01$, respectively. **Significant difference compared to the control group at $p < 0.01$

Table 3 Analysis of factors related to glycosylated hemoglobin control levels

Variable	HbA1c		SMBG frequency		Doctor–patient communication frequency	
	r	p	r	p	r	p
HbA1c	–	–	− 0.208	0.020	− 0.323	0.000
SMBG frequency	− 0.208	0.020	–	–	0.579	0.000
Doctor–patient communication frequency	− 0.323	0.000	0.579	0.000	–	–

comprehensively analyzed 13 mobile medicine apps for diabetes management. Their meta-analysis showed that the use of mobile medicine apps for the management of diabetes can reduce the level of HbA1c by approximately 0.44% compared with the traditional medical group.

Studies have also shown that the higher the frequency of SMBG, the lower the HbA1c value, regardless of the type of treatment the patient receives [9–11]. The negative correlation between SMBG frequency and HbA1c in patients in our study confirms finding, thus reaffirming the importance of blood glucose monitoring.

In this study, patients in both the app-using group and the traditional medical group achieved very good blood glucose compliance rates and higher SMBG frequency; this improvement coincided with the higher

doctor–patient communication frequency. Fjeldsoe [12] promoted health knowledge to patients through mobile devices and found that such information could effectively improve the patient's relevant knowledge level as well as improve the self-management of diabetic patients. Studies by Siminerio et al. [13] showed that the mobile health care model could improve the self-management level and mental state of diabetic patients. The patients participating in the study were well satisfied with the app and showed good, thus obtaining better glycemic control results [13]. Therefore, improving communication between doctors and patients clearly can help patients better self-manage their condition and promotes the achievement of health goals.

A major limitation to our study is that the patients were randomized to either treatment arm, app-based or traditional arm, based on the principle of "voluntarism." This may have increased the possibility of bias in the results of our study. This study design obviously cannot overcome the influence of "patient-subjective psychological factors", but in the current Chinese medical environment (such as Yinao), considering the patient's will first may be the best method to form groups.

CONCLUSION

The diabetes management model based on a medical app is feasible in young T2DM patients, and its implementation in T2DM management in this patient population can result in an improved compliance in terms of treatment and blood glucose control, effectively reducing the HbA1c level in these patients and improving their quality of life and prognosis. In view of the rapid increase in the prevalence of diabetes in China, the mobile medical management model based on an mobile app can help patients self-manage their disease and reduce their disease burden. It can also help doctors to manage patients more comprehensively and systematically, thereby improving their efficiency, which has wide-ranging advantages.

However, medical resources in China are relatively limited compared to those in many developed countries. Although medical apps have reduced the number of patients admitted to hospitals, they have not significantly reduced the workload of doctors. To allow this form of chronic disease management to better serve our country's hierarchical diagnosis and treatment model and to be better used for community hospital patients, we are setting up a human–machine interaction model for diabetes management, which is currently in the machine learning phase. The artificial intelligence management model based on machine learning and human–computer interaction will be the developmental direction of diabetes management in the future. We look forward to working on this approach with colleagues in this field.

as a whole and have given their approval for this version to be published.

Disclosures. There are no commercial associations that might create a conflict of interest in connection with submitted manuscripts. Hong Xu and Hao Yabin have nothing to disclose.

Compliance with Ethics Guidelines. The ethics committee of Beijing Friendship Hospital approved this study. All procedures performed in studies involving human participants were in accordance with the ethical standards of the ethics committee of Beijing Friendship Hospital and with the 1964 Helsinki declaration and its later amendments. Informed consent was obtained from all individual participants included in the study.

Data Availability. The datasets generated and analysed during the current study are not public but are available from the corresponding author on reasonable request.

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REFERENCES

1. Chinese diabetes society. China guideline for type 2 diabetes (the 2017 edition). Chin J Pract Intern Med. 2018;4:292–344.

2. Xu Y, Wang L, He J, et al. Prevalence and control of diabetes in Chinese adults. JAMA. 2013;310(9):948–59.

3. Wang YR, Wang Q, Li LN, et al. Diabetic patients' willingness to use mobile health services and the correlation factors. Chin Gen Pract. 2017;20(13):1619–25.

4. Iyengar V, Wolf A, Brown A, Close K. Challenges in diabetes care: can digital health help address them. Clin Diabetes. 2016;34(3):133–41.

5. Chinese diabetes society. China guideline for type 2 diabetes (the primary hospital edition). Chin J Gen Practitioners. 2013;12(8):675–96.

6. Ray KK, Seshasai SR, Wijesuriya S, et al. Effect of intensive control of glucose on cardiovascular outcomes and death in patients with diabetes mellitus: a meta-analysis of randomised controlled trials. Lancet. 2009;373(9677):1765–72.

7. Xiaohui Guo, Liming Chen, Li Chen, et al. Effectiveness evaluation of the mobile health patients management mode on treatment compliance and glycemic control for type 2 diabetes patients using basal insulin treatment for 12 weeks. Chin J Endocrinol Metab. 2016;32(8):639–46.

8. Marcolino MS, Maia JX, Alkmim MB, Boersma E, Ribeiro AL. Telemedicine application in the care of diabetes patients: systematic review and meta-analysis. PLoS One. 2013;8(11):e79246.

9. Kempf K, Altpeter B, Berger J, et al. Efficacy of the telemedical lifestyle intervention program TeLiPro in advanced stages of type 2 diabetes: a randomized controlled trial. Diabetes Care. 2017;40(7):863–71.

10. Lee JM, Newman MW, Gebremariam A, et al. Real-world use and self- reported health outcomes of a patient-designed do-it-yourself mobile technology system for diabetes: lessons for mobile health. Diabetes Technol Ther. 2017;19(4):209–19.

11. Offringa R, Sheng T, Parks L, Clements M, Kerr D, Greenfield MS. Digital diabetes management application improves glycemic outcomes in people with type 1 and type 2 diabetes. J Diabetes Sci Technol. 2018;12(3):701–8.

12. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. Am J Prev Med. 2009;36(2):165–73.

13. Siminerio L, Ruppert K, Huber K, Toledo FG. Telemedicine for reach, education, access, and treatment (TREAT): linking telemedicine with diabetes self-management education to improve care in rural communities. Diabetes Educ. 2014;40(6):797–805.