An Evaluation of The Impact of Diabetes Medication Therapy Adherence Clinic (DMTAC) in Tangkak

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Abstract

Introduction: The Diabetes Medication Therapy Adherence Clinic (DMTAC) is an ambulatory care service provided by pharmacists to assist diabetic patients in achieving better glycaemic control and medication adherence. Personalised care including counselling and education on medications, disease and lifestyle modifications are provided.

Objective: The objective of this study was to evaluate the impact of DMTAC among poorly controlled diabetic patients at the Tangkak district government health clinics.

Methods: A retrospective cohort study was conducted at Klinik Kesihatan Payamas and Klink Kesihatan sagil. The impact of DMTAC were evaluated in terms of glycaemic control, laboratory parameters and medication understanding. The medication dose, frequency, indication and time (DFIT) score was used to measure patients' medication understanding level. The changes in patients' HbA1c, blood pressure, lipid parameters and DFIT score before DMTAC enrolment and post forth DMTAC visit were determined. Data was analysed using SPSS software.

Results: Eighty DMTAC patients were included in this study. A significant reduction in HbA1c was detected among the patients after receiving at least four DMTAC counselling sessions (mean difference -1.02%, 95% confidence interval (CI) -1.42 – -0.61, $p<0.001$). Medication DFIT score rose from 97.65% to 99.46% (mean difference 1.81, 95% CI 0.71 – 2.91, $p<0.05$) following the completion of at least four DMTAC visits. No statistically significant difference was detected in blood pressure and lipid parameters (total cholesterol, TGL, LDL, HDL) before and post DMTAC visits. A slight decrease in BMI was detected across the study duration, but it was not statistically significant.

Conclusion: This study showed that the DMTAC programme significantly improved glycaemic control and medication understanding among the diabetic patients which could translate into substantial benefits in patient morbidity and mortality as well as savings in health care costs.

Keywords: DMTAC, HbA1c, medication understanding score, diabetic patient, glycaemic control

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Introduction

Diabetes mellitus is a chronic disease caused by insulin deficiency and insulin resistance. It is presented as chronic hyperglycaemia state commonly associated with other metabolic derangements. Poorly controlled diabetes may lead to serious macrovascular and microvascular complications. Diabetes is known to be a multifactorial disease with both non-modifiable and modifiable risk factors. These include genetic, sedentary lifestyle, obesity and unhealthy diet (1).

In recent years, diabetes has become one of the alarming non-communicable diseases due to its rapidly increasing trend. According to the World Health Organization (WHO), the number of adults with diabetes has increased from 108 million in 1980 to 422 million in 2014 globally (1). In line with the global pattern, the National Health and Morbidity Survey 2015 (NHMS V) reported that the prevalence of diabetes among Malaysian adults has reached 17.5% in 2015 compared to 15.2% in 2011 as reported in NHMS IV (2,3). Globally, 12% of the

health expenditures were estimated to be used in diabetes care in 2010. In Malaysia, 16% of the total healthcare cost was estimated to be spent on diabetes in 2010 (4). Despite the huge sum of healthcare budget being spent on diabetes, it is still causing many deaths worldwide. In 2012, 3.7 million deaths worldwide were caused by diabetes and its complications (1).

In view of high impact of diabetes, the Ministry of Health Malaysia (MOH) has introduced Diabetes Medication Therapy Adherence Clinic (DMTAC) service in the primary health clinics and hospitals in 2004. It is an ambulatory care service provided by the pharmacists to help diabetic patients to achieve better glycaemic control and medication adherence level. Diabetic patients with poor glycaemic control, indicated as glycosylated haemoglobin (HbA1c) above 8%, are recruited into the programme either by physicians' referral or identified by the pharmacists. Each patient is scheduled to follow-up with the DMTAC pharmacists for at least 8 sessions according to their medications collection date or check-up appointment date. Personalized cares including medication counselling, education on disease and lifestyle modifications are provided. In addition, DMTAC pharmacists perform blood glucose monitoring during each patient visit. Apart from patient education and counselling, DMTAC pharmacists also work together with physicians in monitoring patient's clinical outcome, treatment regime and any drug related problems (5).

The main objective of DMTAC is to improve patient's medication adherence and subsequently improve patient's glycaemic control. Several studies has shown that better diabetic control could be achieved with higher patient's medication adherence (6,7). The key factors to improve a patient's medication adherence are educational activities, effective communication between the patient and healthcare provider and care continuation (6). A few studies in Malaysia demonstrated that better glycaemic control, improvement in metabolic syndrome indicators and medication understanding level were observed in diabetic patients attending the pharmacist-managed DMTAC services (8-10). Similarly, studies carried out overseas involving pharmacist's interventions in diabetes care had also demonstrated prominent improvement in glycaemic control and cardiovascular risk reduction (11-12).

Although quite a number of studies have demonstrated the impact of DMTAC clinic in Malaysia, more concrete evidence are still needed to support the value of DMTAC in the primary health clinic setting, which caters for more than half (56%) of the diabetes care burden in Malaysia (13). Therefore, the objective of this study was to evaluate the impact of DMTAC among poorly controlled diabetic patients following up at the government health clinics under the Tangkak District Health Office. The impact will be assessed from the aspect of glycaemic control, lipid parameters control, blood pressure control and patient's medication understanding level.

Method

A retrospective cohort study was conducted at the Payamas Health Clinic and Sagil Health Clinic in Tangkak district of Johor to determine the impact of DMTAC services among poorly controlled diabetic patients. Approval from the MOH Medical Research Ethics Committee (MREC) was obtained and this study was registered with the National Medical Research Register (NMRR) with NMRR-18-2616-44167 (IIR)).

All Type 2 Diabetes Mellitus (T2DM) patients with age 18 years and above, HbA1c level above 8.0% who were registered with the DMTACs at Payamas and Sagil Health Clinic and had completed four DMTAC visits between January 2017 to September 2018 were included into the study. Patients who were lost to follow-up, not completing four DMTAC visits or patients who did not have pre-DMTAC and post-fourth DMTAC visit laboratory results, blood pressure and medication understanding score were excluded from the study. Universal sampling method was adopted in this study. All potential subjects were selected, reviewed and became the subjects of this study. Hence, no sample size was calculated.

Patient's DMTAC forms and medical records were reviewed. Patients' demographics data, medication regimens and laboratory parameters were retrieved from the records. The impact of DMTAC was measured as the changes in glycaemic control, lipid parameters control, blood pressure control and patient's medication understanding level. Therefore, the primary outcome was to compare the changes in HbA1c before DMTAC enrolment and post fourth DMTAC visit. The secondary outcomes were to determine the changes in total cholesterol (T.Chl), low-density lipoprotein cholesterol (LDL), high-density lipoprotein cholesterol (HDL), triglycerides (TGL), systolic blood pressure (SBP), diastolic blood pressure (DBP) and patient's medication understanding. The last laboratory and examination results prior to DMTAC recruitment were taken as the pre-

DMTAC parameters, while the most recent results documented during DMTAC visit before September 2018 were taken as post fourth DMTAC visit parameters.

To measure patient's medication understanding and their knowledge to the prescribed medications, assessment via the dose, frequency, indication and time of administration (DFIT) score was used. The score was calculated based on these four elements for every prescribed drug with each element carrying one mark for 'good understanding' and 0 mark for 'unable to understand or recall'. Patients who were able to understand all the four elements of a prescribed drug would score four marks. The total score (denominator) was calculated based on the number of drugs prescribed. The score during the first DMTAC visit was compared to the score during the most recent DMTAC visit before September 2018.

Data was analysed using SPSS software. The difference of the parameters pre-DMTAC and post-fourth DMTAC visit was compared using Paired T-test with the central limit theorem in normality assumption (n>30, normality assumed). A value of $p<0.05$ was taken as statistically significant.

Results

A total of 305 DMTAC records were reviewed and 80 patients (26.2%) were included in this study. The demographic characteristics and anti-diabetic regimens of the patients were presented in Table 1. The mean age of the patients in this study was 56.69 (SD 7.93). Almost 60% of the patients were obese with BMI more than 27.5 kg/m^2 and 30% of the patients were at the pre-obese stage. About half of the patients (48.75%) in this study had diabetes for more than 10 years and 32.5% of the patients were living with diabetes for more than five years. Combination therapy (OHA + insulin) was the most used anti-diabetic regimen among the participants.

Table 1: Characteristics of DMTAC patients (n=80)

Variables	n (%) / mean (SD)
Age, year, mean (SD)	56.69 (7.93)
Gender, n (%)	
Male	26 (32.50)
Female	54 (67.50)
Ethnicity, n (%)	
Malay	50 (62.50)
Chinese	14 (17.50)
Indian	16 (20.00)
Body Mass Index (BMI), n (%)	
<18.5 kg/m^2 (Underweight)	2 (2.50)
18.5-22.9 kg/m^2 (Normal)	7 (8.75)
23.0-27.4 kg/m^2 (Pre-obese)	24 (30.00)
27.5-34.9 kg/m^2 (Obese I)	35 (43.75)
35.0-39.9 kg/m^2 (Obese II)	8 (10.00)
≥ 40 kg/m^2 (Obese III)	4 (5.00)
Duration of Diabetes, year, mean (SD)	9.48 (5.11)
Duration of Diabetes, n (%)	
< 5 years	15 (18.75)
5-10 years	26 (32.50)
>10-20 years	39 (48.75)
Marital Status, n (%)	
Married	77 (96.25)
Not married	3 (3.75)
Anti-diabetic Regimen, n (%)	
OHA only	21 (26.25)
OHA + basal insulin	27 (33.75)
OHA + premixed insulin	25 (31.25)
OHA + basal-bolus insulin	4 (5.00)
Insulin only	3 (3.75)

Abbreviation: BMI – body mass index, OHA – oral hypoglycaemic agent, SD – standard deviation

Table 2: Changes in patient outcomes before DMTAC enrolment and after the fourth DMTAC visit

Variables	Pre-intervention, mean (SD)	Post-intervention, mean (SD)	Mean difference (95% CI)	T-statistics (df) *	P value *
HbA1c, %	10.53 (2.21)	9.52 (1.88)	-1.02 (-1.42, -0.61)	-5.02 (79)	**<0.001**
T.Chl, mmol/L	4.66 (0.90)	4.81 (0.94)	0.15 (-0.042, 0.334)	1.55 (72)	0.126
TGL, mmol/L	1.70 (0.69)	1.76 (0.88)	0.059 (-0.048, 0.165)	1.101 (72)	0.275
LDL, mmol/L	2.68 (0.80)	2.73 (0.80)	0.041 (-0.143, 0.225)	0.445 (72)	0.658
HDL, mmol/L	1.21 (0.30)	1.23 (0.27)	0.0225 (-0.016, 0.061)	1.161 (72)	0.250
SBP, mmHg	134.61 (15.68)	134.36 (19.73)	-0.25 (-4.90, 4.39)	-0.11 (79)	0.915
DBP, mmHg	77.35 (11.62)	77.76 (9.54)	0.41 (-2.46, 3.29)	0.29 (79)	0.776
DFIT score #	97.65 (5.69)	99.46 (2.56)	1.81 (0.71, 2.91)	3.28 (79)	**0.002**
BMI, kg/m^2	29.42 (6.02)	29.38 (5.85)	-0.04 (-0.42, 0.33)	-0.24 (78)	0.811

* paired T-test; # medication understanding score
Abbreviation: T.Chl – total cholesterol; TGL – triglycerides; LDL – low-density lipoprotein cholesterol; HDL – high-density lipoprotein cholesterol; SBP – systolic blood pressure; DBP – diastolic blood pressure; DFIT – dose, frequency, indication and time of administration; SD – standard deviation; CI – confidence interval

Discussion

A small-scale retrospective study conducted at a DMTAC pioneer facility, the Penang Hospital, which involved 43 DMTAC patients who have completed eight DMTAC visits showed a significant improvement in diabetic control and medication adherence level. Significant reductions in HbA1c, fasting blood glucose (FBG) and low-density lipoprotein cholesterol (LDL) were observed (8). Six years later, a prospective open-labelled randomised study at the same hospital which involved a total of 76 patients showed similar positive outcomes (9). In addition to the single-centred studies, a retrospective study involving 56 DMTAC patients in 14 government health clinics in Kuala Lumpur and Putrajaya also showed a remarkable improvement in HbA1c after attending at least four DMTAC sessions. Besides that, patient's medication adherence and medication understanding also improved (10). A large scale randomised controlled trial in the United State with194 patients showed a significant reduction in HbA1c level and blood pressure control after a twelve-month follow up visits with the pharmacists (11). In Australia, a significantly larger improvement in HbA1c level was observed in the intervention group who received DMTAC-like diabetes care by the community pharmacists compared to the control group over 6 months duration (12).

In line with the findings of the few previous studies, this study provided further evidence that DMTAC services run by the pharmacists significantly improved glycaemic control among the poorly controlled diabetic patients. The mean HbA1c reduction was 1.02% pre and post 4th DMTAC visits. One recent study also showed a similar result of 1.03% drop in the mean HbA1c value after four DMTAC sessions with the pharmacists (14). Recognising that these two studies were conducted retrospectively without a control group, a recent meta-analysis with 13 randomised control trials (RCT) from year 2011 to 2015 showed that pharmaceutical care interventions provided by the pharmacists were effective in reducing the HbA1c among T2DM patients (15). Another systematic review with meta-analysis which included 16 both randomised and non-randomised controlled clinical trials also showed that pharmacist's interventions consisting of diabetes education and medication management significantly reduce HbA1c over control. The magnitudes of HbA1c reduction were greater when the average baseline HbA1c values were above 9%. This could possibly explain the greater reduction of HbA1c in our study compared to the meta-analysis (16).

HbA1c is an important indicator of glycaemic control in diabetic patients over time. Glycaemic control is closely associated with the incidence of diabetic complications. According to the UK Prospective Diabetes Study (UKPDS) 35, every 1% reduction in HbA1c was associated with 21% risk reduction in any end point of death related to diabetes and 37% decrease in the risk for microvascular complications (17). This is particularly important for the diabetic patients with high HbA1c.

The average baseline HbA1c value in this study (10.53%) was similar to that reported in a recent study conducted at a government health clinic in Johor Bahru, Malaysia (10.61%) (14). These values were higher than the mean HbA1c value among patients treated at hospital-based outpatient diabetic clinic in Malaysia

reported by Mafauzy *et al.* in 2013 which was 8.52% (SD 2.01%) (18). A higher mean value of HbA1c among the patients at government primary health clinics could possibly be due to the limited choice of antidiabetic drugs available. This was shown in the study where hospital have recorded an increase use of Dipeptidyl Peptidase-4 (DPP-4) Inhibitors and analogue insulin, in contrast to the primary health clinics where both drugs are still restricted to be prescribed by the Family Medicine Specialists (FMS) with limited quota allocated. Besides, the low usage (6.25%) of intensive insulin regimens in this study compared to 20.6% in the hospital setting could also explain the higher mean HbA1c value in our patients (18).

According to UKPDS 35, besides glycaemic control, dyslipidaemia, hypertension and smoking also contributed to the cardiovascular risk in diabetic patients (17). Therefore, blood pressure and lipid level control are important in preventing diabetes complications. UKPDS 36 showed that every 10mmHg decrease in the SBP was associated with 12% risk reductions in diabetes related complications, 15% deaths related to diabetes, 11% myocardial infarction and 13% microvascular complications. SBP below 120mmHg was presented with the lowest risk (19).

The implication of pharmacist care on blood pressure control tends to give many different results. A systematic review and meta-analysis of RCTs showed greater reductions in both SBP and DBP among diabetic outpatients who received pharmacist care compared to usual care (20). A recent meta-analysis involving 39 RCTs with 14,224 outpatients has also shown positive outcome in supporting the pharmacists' interventions in improving SBP and DBP control. However, the effect sizes of the pharmacists' interventions on blood pressure control in the individual studies varied from tremendous effect to modest or no effect (21). Similar to our study, a recent study about DMTAC at the Mahmoodiah Health Clinic in Johor, Malaysia also showed no significant changes in blood pressure control (14). One of the possible reasons for this could be the baseline blood pressure in both studies were closely around the recommended target level of blood pressure (135/75mmHg) in the Malaysian Clinical Practice Guidelines (CPG) on Management of Type 2 Diabetes Mellitus (22).

Like blood pressure control, pharmacists' care on the control of cholesterol level also produced a mixed result. Although a meta-analysis demonstrated statistically significant reductions in LDL with pharmacist care, it was with moderate heterogeneity. No statistically significant change in HDL cholesterol was detected in the meta-analysis (20). Similar to our study, the DMTAC study at Mahmoodiah Health Clinic also failed to show a significant change in the lipid level (14). No significant changes in the lipid levels could possibly be due to our baseline lipid profiles that was already meeting the recommended levels for diabetic patients without overt cardiovascular disease in the Malaysian CPG (22). Another possible reason could be due to the infrequent lipid monitoring with an average frequency of once per year causing the delay in optimum treatment. Lastly, the limited anti-dyslipidaemia agents available at the health clinic setting may also contribute to this. The only medication available is Simvastatin tablet with the recommended daily dose of 20-40mg that confers moderate intensity therapy. Agents for high intensity therapy such as Atorvastatin was still restricted to the use by FMS (23).

High calorie diets and sedentary lifestyle are the known risks factors for T2DM. About 90% of the patients recruited in this study were pre-obese or obese. The absence of significant reduction in BMI in this study could possibly due to the poor adherence with lifestyle recommendations provided. A study showed that it was highly prevalent among Malaysian T2DM patients to be non-adherent to the lifestyle modifications suggested (24). Another study showed that only 16.4% of individuals with diabetes adhered to the dietary regimen provided by the dietitians (25). Besides that, it was reported that 54% of Malaysian adults with diabetes were physically inactive (26). In a study conducted among T2DM patients at the Cheras Health Clinic in Kuala Lumpur, only 20% reported practicing high physical activity level with the rest adopting either moderate physical activity level (47%) or low physical activity level (33%) (27). The inefficacy of pharmacist care in reducing BMI was also reported in other DMTAC studies (9,14). Although a meta-analysis of two studies showed a statistically significant benefit of pharmacist care in BMI reduction, there was substantial heterogeneity between studies (20).

As reported in other DMTAC studies, our findings showed that patient's medication understanding score was significantly improved after DMTAC visits (10,14). Medication review done by the pharmacists during the DMTAC sessions had helped the patients to improve their medication knowledge. Longer patient contact time also enabled the pharmacist to reinforce necessary information and subsequently improving their understanding, especially for patients with multiple medications and older age patients (28). A study done in

Singapore by Goh *et al.* (29) demonstrated that the better knowledge and understanding about own medication were found to be beneficial to enhance patients' medication adherence and could ultimately lead to the improvement in glycaemic control.

Several limitations were identified in this study. Small sample size was one of it. This restricted the extrapolation of the finding of this study to the entire diabetic patient population. Besides, as a retrospective observational study, a control group with standard care was not available for comparison to assess the effectiveness of DMTAC programme. The effect of education on metabolic control of diabetic patients may decrease over time after the end of the intervention (22). Future studies should be conducted with a longer follow up period to determine if the impact of DMTAC counselling sessions could sustain after patients were discharged from the DMTAC. Also, larger RCTs that are adequately powered are needed to evaluate the effectiveness of DMTAC programme in metabolic control and to determine the appropriate follow up duration of the DMTAC programme for more sustained positive impact.

Conclusion

As a conclusion, the DMTAC programme can help in improving the glycaemic control and medication understanding among diabetic patients. These positive impacts may translate into substantial benefits in improving patient morbidity and mortality as well as savings on health care cost.

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Conflict of Interest Statement

No external funding was received and the authors declared no conflict of interest.

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