ORIGINAL RESEARCH

Impact of Attendance to a Pharmacist-Managed Medication Adherence Clinic on Glycemic Control and Risk Factors for Non-Completion Among Persons with Type 2 Diabetes Mellitus in Selangor, Malaysia

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Background: Diabetes mellitus (DM) is a chronic metabolic disorder affecting millions globally. Adherence to treatment is crucial for effective management.

Objective: To compare clinical outcomes, specifically changes in haemoglobin A1c (HbA1c) and fasting blood sugar (FBS) levels, between DM patients who completed the pharmacist-managed Diabetes Medication Therapy Adherence Clinic (DMTAC) sessions and those who did not, and to identify risk factors associated with non-completion of DMTAC.

Methods: This multicenter, retrospective study included patients with DM attending DMTAC at five Ministry of Health centers from January 2018 to December 2020. Patients were categorized based on their completion of DMTAC sessions: those who completed at least four sessions and those who did not as per DMTAC protocol. The changes in HbA1c and FBS levels between the groups were analyzed. Logistic regression was employed to identify risk factors for non-completion of DMTAC.

Results: A total of 198 patients were included, comprising 49% male with a mean age of 56.52, ±12.91 years. The complete group consisted of 49% (n=99) of the patients, while the did not complete group included 50.5% (n=100). A statistically significant reduction in FBS levels from initial to final measurements was observed in the complete group compared to the did not complete group (P=0.024). Female gender, higher education levels, and a longer duration since DM diagnosis were significantly associated with non-completion of DMTAC.

Conclusion: Diabetic patients attending at least four DMTAC sessions showed potential improvements in FBS levels. To enhance attendance at DMTAC sessions, healthcare professionals should focus on patients identified with risk factors for non-completion of DMTAC.

Keywords: pharmacist-managed clinic, glycemic control, HbA1c, medication adherence, type 2 diabetes mellitus

Introduction

The global prevalence of diabetes mellitus (DM) is escalating.[1] By 2030, this prevalence is expected to increase by 42% in developed countries and a striking 170% in developing countries.[2] This trend is particularly alarming in developing regions, attributed to rapid population growth, aging populations, unhealthy local diets, urbanization, increasing obesity rates, unhealthy lifestyles, and limited access to adequate healthcare.[3] As these challenges grow, so does the cost of managing the disease, prompting the development of strategies for early diagnosis, effective care, and primary prevention.[4] In response to this escalating crisis, various pharmacist-led intervention programs have been implemented globally. These include Medication Therapy Management (MTM),[5] Medicine Use Reviews (MUR),[6] Home Medication

Reviews (HMR),[7] and Medication Therapy Adherence Clinics (MTAC).[8] Each of these programs shares a common goal: to improve patient adherence to treatment and enhance overall treatment outcomes.

Specifically in Malaysia, the Diabetes Medication Therapy Adherence Clinic (DMTAC) program was established in 2004, focusing on patients with diabetes. Pharmacists in this program are required to complete training as mandated by the Malaysian Ministry of Health, and the program is governed by protocols and service modules updated periodically by the Pharmaceutical Services Program.[9] Eligible patients for DMTAC are those receiving treatment in hospitals and health clinics, identified by criteria such as uncontrolled diabetes, issues with medication adherence, and failure to meet individual HbA1c targets. The protocol requires each patient to attend a minimum of four appointments and demonstrate a medication-related knowledge score of 100%, as measured by the DFIT score (dosage, frequency, indication, time, and exhibit good medication adherence to be eligible for discharge from the service. They are also required to achieve targeted HbA1c results in at least two readings. Patients may be discontinued from the service if they fail to attend for six consecutive months or miss three consecutive sessions. These criteria are established to ensure the realistic achievement of set objectives.

Numerous studies have evaluated the effectiveness of DMTAC in achieving optimal diabetes control and medication adherence.[10–16] These studies recruited diabetes patients and compared outcomes between those who completed their DMTAC appointments, those who did not, and patients who were not enrolled in the DMTAC service. However, their limitations included being conducted at single centers and involving small sample sizes. Additionally, a systematic review involving 18 studies highlighted a significant patient dropout rate from the DMTAC program.[15] To date, no research has specifically focused on identifying the factors that influence patient attendance at DMTAC, revealing a critical gap in the information necessary to enhance the service. This gap underscores the need for an assessment of DMTAC's effectiveness on a larger, more diverse sample and an investigation into the factors associated with patient attendance and appointment adherence. The aim of this study is to assess the outcomes of the current DMTAC service by comparing regular attendees with those who have missed appointments. The insights gained from this research will contribute to developing sustainable improvements for the DMTAC service.

Materials and Methods

The study was conducted through a retrospective analysis of patient records who attended the DMTAC program from January 2018 to December 2020 at three health clinics and two hospitals in the state of Selangor, Malaysia. Ethical approval for this study was obtained from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (NMRR-19-3816-5209). The requirement for obtaining informed consent from patients was exempted because all collected data were completely anonymized, adhering to the ethical standards set forth in the Declaration of Helsinki. The reporting of this study aligns with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines specific to cohort studies.[17] A list of patients with type 2 diabetes, aged ≥ 18 years, who attended at least one DMTAC session during the period from January 2018 to December 2020, was screened for inclusion as study samples. Patients were excluded from the study if they had no HbA1c level measurements during the study period, HbA1c measurements taken less than three months before the first DMTAC session, HbA1c measurements taken more than one year after the last DMTAC session, or if they had incomplete records. The patients were divided into two groups: (1) those who completed and (2) those who did not complete. The complete attendance group consisted of patients who attended the DMTAC program for a minimum of four sessions (≥ 4 sessions), while the did not complete group comprised those who missed follow-up sessions before the fourth session (< 4 sessions), in accordance with the criteria outlined in the published DMTAC protocol.[9] Patient data were retrospectively collected from medical records using a data collection form, employing convenience sampling method.

In a previous study conducted by Butt et al (2016) at a teaching hospital in Kuala Lumpur, it was found that the data in each group of patients tested had a normal distribution with a standard deviation (SD) of 1.8.[18] Assuming a true minimum difference in HbA1c between the control group and the test group of 1, estimates calculated through the "PS" software indicated that a total of 69 samples were required in each group to reject the null hypothesis that the population means between the two groups were equal with a probability (power) of 0.9. With an estimated 35% of incomplete data, the minimum required sample size was 190 samples, or 95 samples for each group.[19] In assessing the risk factors for non-

completion at the clinic, this research follows the guidelines set by Green (1991) regarding the appropriate sample size for examining individual predictors in regression analysis.[20] The author recommends the formula N > 104 + M to determine the sample size, where N represents the sample size and M is the number of independent variables involved. In this study, the logistic regression analysis incorporates eight independent variables. Consequently, based on Green's formula, the minimum required sample size is calculated to be 112.

The primary outcome evaluated in this study was the change in clinical outcomes from the initial (baseline) to the final DMTAC session. Clinical outcomes included glycemic control parameters such as the most recent readings of HbA1c and fasting blood sugar (FBS). HbA1c is an accurate indicator of glycemic control over the three months preceding a measurement.[21] A HbA1c level > 7% indicates poor glycemic control.[22] All reported medication adherence levels were recorded irrespective of the assessment tool used by the pharmacists. Medication knowledge scores were assessed for each patient's DMTAC visit.

Descriptive statistics were reported for the entire population and separately between two groups, namely the complete and incomplete attendance groups. Categorical variables were summarized using frequencies, percentages, and continuous variables as means [standard deviation (SD)] for age, duration of diabetes diagnosis, number of medications, comorbid diagnoses, HbA1c readings, and FBS readings. Medians [interquartile range (IQR)] were used for gender, ethnicity, educational level, employment status, and medication adherence levels. Normal distribution for continuous variables was tested using the Kolmogorov–Smirnov method. For group comparisons, the Student's *T*-test was used for continuous variables, and the chi-square test was used for categorical variables.

A two-way repeated measures ANOVA was used to assess changes at two time points and differences between groups for HbA1c and FBS measurements. The Wilcoxon signed-rank test was used to compare medication adherence means between initial and final adherence for both groups. Binary logistic regression was employed to identify potential risk factors and associations for DMTAC non-completion. Odds ratios (OR) and corresponding 95% confidence intervals were calculated for all variables. Statistical analysis was conducted using IBM SPSS Statistics version 21.0.[23] All statistical tests were two-tailed, and a value of $p < 0.05$ was considered statistically significant.

Results

An analysis of the patient database across all participating facilities revealed that 198 patient profiles met the specified criteria and were subsequently included in this study. Of these, 49% (n=98) of patients completed a minimum of four DMTAC sessions (complete) while 50.5% (n=100) attended fewer than four sessions (did not complete). The average age (SD) for the entire cohort was 56.52 (12.91) years, and 97 patients (49.0%) were male (Table 1). The majority identified as Malay (n=99, 50.0%), had an unspecified level of education (n=72, 36.4%), and were not employed (n=111, 56.1%). There were no significant differences between the complete and did not complete groups at baseline regarding socio-demographic, clinical characteristics, and demographic features, except for Malay ethnicity (n=99, 50.0%, P = 0.018).

For the complete group, HbA1c measurements were significantly different between the first measurement (10.83; 95% CI: 10.31-11.34) and the last measurement (9.61; 95% CI: 9.13-10.09) (P < 0.001) (Table 2). For the did not complete group, HbA1c measurements were also significantly different between the first measurement (10.40; 95% CI: 9.84-10.97) and the last measurement (9.94; 95% CI: 9.42-10.47) (P < 0.029). There was no statistically significant difference in HbA1c levels between the complete group and the did not complete group at the beginning of the test. Likewise, there was no statistically significant difference in HbA1C between the complete group and the did not complete group at the end of the test.

For the complete group, FBS measurements were statistically different between the first measurement (10.14; 95% CI: 8.97-11.31) and the last measurement (7.73; 95% CI: 6.67-8.79) (P < 0.001) (Table 2). In contrast, for the did not complete group, FBS measurements showed no statistically significant difference between the first measurement and the last measurement. FBS values were not significantly different between the complete group and the did not complete group at the beginning of the test. However, FBS values were significantly different between the complete group and the did not complete group at the end of the test (P = 0.024).

The Friedman test was utilized alongside the repeated measures ANOVA to analyze the data, particularly because some datasets were non-normally distributed. This non-parametric test was specifically applied to examine the did not complete group. It supported the findings of the repeated measures ANOVA by demonstrating significant changes over

Table 1 Distribution of Subjects According to Sociodemographic and Clinical Characteristics (N=198), Malaysia

Characteristics	All patients (N=198)	Complete (n=98)	Incomplete (n=100)	P values
Number of visits (mode)		4	1	
Baseline characteristics				
Age, years, mean (SD)	56.5 (12.9)	58.0 (12.9)	55.0 (12.8)	0.103
Male	97 (49.0)	59 (54.6)	38 (42.2)	0.063
Race				
Malay	99 (50.0)	43 (43.8)	56 (56.0)	0.018
Chinese	37 (18.7)	26 (26.5)	11 (11.0)	
Indian	62 (31.3)	29 (29.6)	33 (33.0)	
Years diagnosed, mean (SD)	10.43 (8.0)	9.3 (7.4)	11.6 (8.5)	0.051
Numbers of medications	5.86 (2.1)	5.8 (2.0)	5.9 (2.3)	0.701
Concurrent diagnosis	2.6 (0.1)	2.7 (0.9)	2.5 (1.0)	0.200
DFIT Score, mean (SD)	93.3 (9.6)	93.6 (9.3)	93.0 (9.9)	0.668
HbA1c, %, mean (SD)	10.6 (2.2)	10.7 (2.3)	10.5 (2.2)	0.747
FBS, mmol/l, mean (SD)	20.9 (4.2)	9.6 (3.3)	11.6 (4.6)	0.055
Education				
Primary	34 (17.2)	19 (19.4)	15 (15.0)	0.417
Secondary	57 (28.8)	29 (29.6)	28 (28.0)	
Tertiary	35 (7.7)	13 (13.3)	22 (22.0)	
Unknown	72 (36.4)	37 (37.8)	35 (35.0)	
Working status				
Working	82 (41.4)	38 (38.8)	44 (44.0)	0.066
Not working	111 (56.1)	55 (56.1)	56 (56.0)	
Unknown	5 (2.5)	5 (5.1)	0 (0.0)	
Adherence				
Poor	70 (35.4)	37 (39.4)	33 (33.0)	0.368
Moderate	104 (52.5)	50 (53.2)	54 (54.0)	
Good	20 (10.1)	7 (7.4)	13 (13.0)	
Unknown	4 (2)	4 (0.0)		

Notes: All values are reported as no.(%) unless otherwise noted.
Abbreviations: DFIT, medication dosage, frequency, indication, and timing; FBS, fasting blood sugar level; HbA1c, target glycated haemoglobin level; SD, standard deviation.

Table 2 Clinical Measures for Mean Scores and Adjusted Mean Scores for Clinical Outcome Measures Among Adult Diabetic Patients

	N	Descriptive Statistics		Adjusted Mean		P value
		Mean (SD)		Mean (95% CI)		
		First Measurement	Final Measurement	First Measurement	Final Measurement	
a. HbA1C (n=156)						
Complete group	85	10.83 (2.52)	9.61 (2.24)	10.83 (10.31,11.34)	9.61 (9.13,10.09)	<0.001
Incomplete group	71	10.40 (2.28)	9.94 (2.22)	10.40 (9.84, 10.97)	9.94 (9.42, 10.47)	0.029
Between group differences, P value		–	–	0.273	0.360	
a. FBS (n=63)						
Complete group	42	10.14 (3.86)	7.73 (3.06)	10.14 (8.97,11.31)	7.73 (6.67,8.79)	<0.001
Incomplete group	21	9.85 (3.61)	9.84 (4.08)	9.85 (8.20, 11.50)	9.84 (8.35, 11.34)	0.996
Between group differences, P value		–	–	0.775	0.024	

Abbreviations: CI, confidence interval; FBS, fasting blood sugar level; HbA1c, target glycated haemoglobin level; SD, standard deviation.

time, as indicated by a p-value of <0.001. In addition, baseline FBS measurements were analyzed for between-group comparisons, yielding a p-value of 0.610. This result suggested no significant statistical differences between the groups at the study's inception. However, a distinct shift was observed in the final FBS measurements. The analysis of these concluding measurements indicated a statistically significant difference between the groups, as evidenced by a p-value of 0.037. This implies that while the initial FBS levels were similar across the groups, by the end of the study period, significant disparities in FBS levels had developed.

For the complete group, the highest percentage of samples that had moderate medication adherence in the first measurement showed the greatest improvement to good adherence in the last measurement (38.3%). Meanwhile, for the did not complete group, the highest percentage of samples was those with the same moderate adherence level in both the first and last measurements (42.0%). There was a significant change in medication adherence between the first and last measurements (P < 0.001) for both the complete and did not complete groups (Table 3).

A logistic regression analysis was conducted to identify risk factors associated with DMTAC non-completion (Table 4). Among the sociodemographic and clinical characteristics included in this analysis, it was found that gender,

Table 3 Comparison of Level of Medication Adherence According to DMTAC Session

Groups			Adherence (Final)			P value[a]
			Poor	**Moderate**	**Good**	
Complete (n=94)	Adherence (First)	Poor	6 (6.4%)	21 (22.3%)	10 (10.6%)	<0.001
		Moderate	2 (2.1%)	12 (12.8%)	36 (38.3%)	
		Good	0 (0.0%)	1 (1.1%)	6 (6.4%)	
Incomplete (n=100)	Adherence (First)	Poor	20 (20.0%)	11 (11.0%)	2 (2.0%)	<0.001
		Moderate	0 (0.0%)	42 (42.0%)	12 (12.0%)	
		Good	0 (0.0%)	2 (2.0%)	11 (11.0%)	

Notes: [a]Wilcoxon Signed Ranks test was applied to compare the first and final adherence.
Abbreviation: DMTAC, diabetes medication therapy adherence clinic.

Table 4 Multivariate Analysis of Factors Associated with for Not Completing DMTAC Session

Variables	B(SE)	Adjusted OR (95% CI)	Wald (df)	P value
Female		Ref.		
Male	−1.06(0.46)	0.35(0.14,0.85)	5.31(1)	0.021
Race				
Indian		Ref.		
Malay	0.55(0.42)	1.73(0.76,3.91)	1.73(1)	0.189
Chinese	−0.66(0.53)	0.52(0.18,1.47)	1.53(1)	0.216
Age	0.00(0.02)	1.00(0.96,1.03)	0.04(1)	0.850
Education Level				
Tertiary		Ref.		
Unknown	−0.80(0.57)	0.45(0.15,1.35)	2.03(1)	0.154
Primary	−1.28(0.65)	0.28(0.08,0.99)	3.89(1)	0.049
Secondary	−0.98(0.58)	0.38(0.12,1.17)	2.86(1)	0.091
Working status				
No		Ref.		
Yes	0.33(0.49)	1.39(0.53,3.61)	0.45(1)	0.504
Unknown	NE	NE	NE	NE
Years diagnosed with diabetes	0.06(0.03)	1.06(1.01,1.11)	5.18(1)	0.023
Concurrent diagnosis	−0.01(0.19)	0.99(0.68,1.45)	0.00(1)	0.973
HbA1C level at DMTAC first session	−0.05(0.08)	0.95(0.80,1.12)	0.41(1)	0.523

Abbreviations: B, logistic regression coefficient; CI, confidence interval; df, degree of freedom; DMTAC, diabetes medication therapy adherence clinic; HbA1c, target glycated haemoglobin level; NE, not estimable; OD, odds ratio; Ref., reference group; SD, standard deviation; SE, standard error.

education level, and duration since diabetes diagnosis were significantly related to DMTAC non-completion ($P < 0.05$). Male patients were found to be 65.20% less likely to miss DMTAC appointments compared to female patients after adjusting for all factors (OR = 0.35; 95% CI = 0.14, 0.85). Patients with lower education levels were also found to have a 72.30% lower risk of DMTAC non-completion compared to patients with higher education levels after adjusting for all factors (OR = 0.28; 95% CI = 0.08, 0.99). Additionally, for each year increase in the duration since diabetes diagnosis, patients had a 1.06% higher risk of DMTAC non-completion (OR = 1.06; 95% CI = 1.01, 1.11). No significant associations were found between age, employment status, and the number of comorbid diagnoses with DMTAC non-completion.

Discussion

The study aimed to assess the impact of patients' completion in the DMTAC program on blood glucose control (HbA1c and FBS levels) and medication adherence, while also identifying associated risks with DMTAC program non-completion. Five facilities were involved in this study, and a total of 198 patient records attending during the study period were analyzed. No differences were found in baseline patient characteristics between the two groups under study, except for ethnicity. Malay patients constituted the largest group in the study, which was expected since the study used a convenient sampling technique, and Malays make up the majority ethnic group in Malaysia (51%).[24] In most studies involving patient record sampling, it's common to observe a higher representation of Malay patients.[25,26]

The study revealed significant changes between the initial and final measurements of HbA1c levels in both the complete and did not complete groups, indicating improved glycemic control when patients attended DMTAC. A study conducted in Kedah, Malaysia, showed that the total number of DMTAC sessions had no impact on the final HbA1c outcomes of patients.[10] This may suggest that some patients could benefit from fewer DMTAC sessions, particularly if the conducted sessions can focus on addressing the specific problems of individual patients. Additionally, the study found that patients who attended at least four DMTAC sessions exhibited a stronger association with better FBS levels when compared to the did not complete group. However, it is worth noting that no significant changes were observed in HbA1c levels. This lack of significant findings could potentially be attributed to the small sample size, which consisted of only 21 individuals in the complete group with final HbA1c readings. Additionally, it is important to consider that FBS levels were measured on the final visit itself, whereas HbA1c might have been measured weeks or even months after the final visit. This difference in timing may reflect a more accurate impact of short-term glucose control. Furthermore, it is essential to acknowledge that participants who completed the required visits may have been discharged from the DMTAC or may not have returned for follow-up visits after completing their initial four visits. As a result, they could potentially experience a reduction in HbA1c levels over time. However, this reduction may not have reached statistical significance when compared to the did not complete group, as the frequency of their visits would have decreased.

Furthermore, the study identified that among patients who fully attended DMTAC services, those with a moderate level of medication adherence were the most likely to improve to a higher adherence level in their last DMTAC session. The analysis also indicated differences in medication adherence rates among patients between the complete attendance and attrition groups. More patients achieved good and moderate medication adherence by the end of DMTAC sessions in the complete attendance group compared to those who dropped out. These findings illustrate the effectiveness of DMTAC in improving patients' medication adherence rates. These results are consistent with other studies that have investigated the effectiveness of DMTAC in enhancing medication adherence among patients.[10–13,15,16] However, a network meta-analysis suggested that the most effective intervention strategies for long-term medication adherence should encompass multiple components, including technical aspects of behavior change.[27]

Additionally, this study was able to assess several factors associated with DMTAC program non-completion. The analysis revealed that male patients were less likely to drop out from DMTAC services. This factor may be related to local sociocultural factors, and similar findings have been reported in several other studies examining patient attendance rates for healthcare appointments.[28–31] Furthermore, the analysis indicated that patients with lower levels of education

were at a reduced risk of attrition from the services. This is likely because individuals with lower education levels have limited access and capabilities to seek information about medications and diseases independently.[32] Therefore, patients in this category have a greater incentive to attend appointments to obtain better information about their condition. However, even though patients with higher levels of education possess more knowledge and understanding of their condition, this does not necessarily translate into better treatment adherence.[33]

The findings of this study have demonstrated the positive impact of pharmacist-led services on diabetes management. However, these findings need to be interpreted with caution due to certain limitations. One significant limitation of this study is that retrospective data collections are susceptible to variations in data completeness and quality when compared to the rigorous data collection protocols typically found in prospective studies, such as clinical trials. Additionally, given that the study was conducted across multiple centers, there was no centralized protocol for measuring HbA1c (glycated hemoglobin) and FBS (fasting blood sugar). This lack of standardization resulted in variations in the strategies used to measure blood glucose control at each facility. Consequently, a considerable number of samples had to be excluded from the analysis due to the unavailability of data, particularly for HbA1c. Furthermore, despite the inclusion of facility-related factors in the analysis, there remains a possibility that the effectiveness of the intervention program is strongly influenced by the skills of the individuals overseeing the program. This introduces an additional layer of complexity when interpreting the results.

Conclusion

In conclusion, this study highlights the positive impact of pharmacist-led DMTAC services on diabetes management, demonstrating improvements in FBS and adherence among patients attending at least four sessions. Additionally, the study identified several factors associated with DMTAC non-completion, including female gender, higher educational level, and longer duration since diabetes diagnosis. These findings emphasize the importance of tailoring interventions to address specific patient needs and challenges, ultimately contributing to the enhancement of diabetes care and patient outcomes. Further research and the development of standardized measurement protocols are warranted to validate and build upon these results.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author, EH, upon reasonable request.

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Disclosure

The authors report no conflicts of interest in this work.

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