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IMPACT OF PHARMACIST-MANAGED DIABETES MEDICATION THERAPY ADHERENCE CLINIC (DMTAC) IN GOVERNMENT HEALTH CLINICS

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Pharmacist-managed DMTAC has been set up in Malaysia government healthcare facilities to assist diabetic patients in improving their medication adherence level and glycaemic control. The aim of this study is to determine the effect of pharmacist involvement in a DMTAC programme on patient glycaemic control in 14 government health clinics in Kuala Lumpur and Putrajaya. This multi-centre retrospective study collected DMTAC patient demographics, medication regimens, glycated haemoglobin ($HbA1_c$) levels, Modified Morisky Medication Adherence Scale (MMMAS) data, and percentages of understanding towards their medications (based on information retrieved and reviewed from their DMTAC booklets). The data were analysed using IBM SPSS Statistics Version 21.0. Fifty six patients were involved in this study. The mean $HbA1_c$ reduction (SD) of the pre- and post-intervention groups showed a statistically significant improvement of 1.0% (1.70) ($p<0.001$); decreasing from 10.7% (1.51) pre-intervention to 9.7% (1.75) post-intervention. The mean medication understanding score for the post-intervention group was 97.6% (7.32), which was significantly higher than the pre-intervention group score of 92.2% (13.61) ($p = 0.005$). The mean MMMAS of the post-intervention group was 7.4 (1.19), which was significantly higher than the pre-intervention group mean MMMAS of 6.5 (2.33) ($p = 0.001$). This study demonstrated an improvement in glycaemic control, medication understanding, and adherence level among T2DM patients who were enrolled in a pharmacist-managed DMTAC programme.

Keywords: Diabetes, Diabetes Medication Adherence Therapy Clinic (DMTAC), Endocrine, Pharmacist, $HbA1_c$, Medication adherence, Medication understanding

INTRODUCTION

Diabetes has become a major global health problem. According to the World Health Organization (WHO), the worldwide prevalence of diabetes is estimated to increase from 2.8% in 2000 to 4.4% in 2030 for all age groups (Wild *et al*. 2004). In Malaysia, the total prevalence of diabetes mellitus (known and newly diagnosed) was 11.6% in 2006 (Letchuman *et al.* 2010). This increase in the number of people with diabetes mellitus would cause a tremendous burden on health care systems because poorly controlled diabetes can lead to many micro- and macro-vascular complications (American Diabetes Association, 2014).

$HbA1_c$, a form of glycosylated haemoglobin used to measure patients' glycaemic control over the past three months, is a clinical outcome used as a guide to determine patients' medication adherence level and understanding of their medications and to adjust

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diabetes medication doses. The Malaysian Clinical Practice Guideline recommends an optimum $HbA1_c$ level of less than 6.5% for type 2 diabetes mellitus (T2DM) patients (Ministry of Health Malaysia 2009). Mayberry and Osborn (2012) and Rozenfeld *et al.* (2008) showed that better adherence to medications improves glycaemic control and $HbA1_c$ levels in patients with T2DM. However, improving patients' medication adherence is the main challenge in healthcare settings.

To improve glycaemic control, Diabetes Medication Therapy Adherence Clinics (DMTACs) were set up in Malaysia government healthcare facilities starting in 2006 with the aim of assisting diabetic patients in improving their medication adherence level and glycaemic control (Lim and Lim 2010). In this ambulatory care service, pharmacists collaborate with physicians providing the services. Patients with poor glycaemic control are enrolled into a DMTAC and undergo follow up counselling sessions for a minimum of four visits. During every visit, the patients undergo a medication adherence assessment involving the Modified Morisky Medication Adherence Scale (MMMAS), medication understanding evaluation, identification, and management of drug related problems, medication counselling, monitoring of clinical outcomes, and diabetes education by the pharmacist (Morisky *et al*. 2008; Lim and Lim 2010; Ministry of Health Malaysia 2010). Glycaemic clinical outcomes including $HbA1_c$, fasting blood sugar, and random blood sugar are monitored (Lim and Lim 2010).

A non-randomized prospective study conducted by Cioffi *et al*. (2004) in 70 veterans affairs patients used a model similar to DMTAC and found that after 9 to 12 months of participation, the $HbA1_c$, systolic and diastolic blood pressure, total cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides, and level of microalbuminuria significantly decreased. A systematic review by Machado *et al.* (2007) found that the meta-analysis of data from 2247 patients in 16 studies showed that the $HbA1_c$ levels were significantly reduced in the pharmacists' intervention group compared to the control group. Pharmacists' interventions further reduced $HbA1_c$ values over the control (Machado *et al.* 2007). These reviews further proved that pharmacists' interventions are important in improving patients' glycaemic control.

In Malaysia, the effectiveness of DMTAC in improving patients' glycaemic control remains under debate because the data are limited. Although Lim and Lim (2010) showed that DMTAC was effective in improving patient outcomes, his study was performed in a hospital setting and is the only study of its kind in Malaysia. Several studies have shown that by providing such a clinical pharmacy service to the diabetes patients, improvements in the $HbA1_c$, fasting blood glucose level, medication compliance, and understanding of medication of diabetes patients could be achieved. This study would be able to determine the impact of pharmacist's involvement in a DMTAC programme on patients' glycaemic control via the monitoring of several significant parameters, including the $HbA1_c$ level, MMMAS and percentage of medication understanding, amongst the government health clinic patient population, whose demographics might differ from the population of a tertiary hospital setting in the Lim and Lim (2010) study.

One of the aims of this study was to determine patients' glycaemic control, understanding towards their medication, and medication adherence in patients with T2DM who had enrolled in a DMTAC programme in government health clinics in Kuala Lumpur and Putrajaya. This study was also conducted to evaluate the impact of pharmacist-managed DMTAC programmes amongst these government health clinics. The retrospective data that were available in our current DMTAC database would be analysed to observe the DMTAC patients' performance in these government health clinics.

METHODS

A retrospective, multi-centre study of the DMTAC programme was conducted in government health clinics in Kuala Lumpur and Putrajaya. Patients with T2DM from these government health clinics in Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur & Putrajaya (JKWPKL&P) who were enrolled in the DMTAC programme were recruited into this study. These patients were recruited based on the following inclusion and exclusion criteria.

The inclusion criteria were Malaysians aged 18 years and older who had $HbA1_c$ levels above 8% and who had completed at least 4 visits with the DMTAC pharmacists within the period from 1 January 2013 and 30 April 2014. Patients with end stage renal failure (ESRF) were excluded from this study.

All medical records and DMTAC booklets were retrieved and reviewed. These records provided information about patient demographics, medication regimens, and laboratory parameters, including $HbA1_c$ levels. Records regarding patients' adherence using MMMAS and assessments of patients' understanding towards their medications were included. For medication understanding assessments, patients were assessed on their knowledge of the correct dosage, frequency, indication, and timing of administration of every drug listed on their prescription on every visit. For every accurate answer, a 'tick' would be written in the column of the assessed question. The percentage of medication knowledge was calculated based on the number of 'ticks' obtained over the total number of ticks that could be obtained from all the medications on the prescription. Interventions done by pharmacist with prior agreement from the doctors were included in the data to review the effect of pharmacists' interventions on patients' glycaemic control.

The primary outcome was to determine the mean difference in the $HbA1_c$ level, MMMAS and percentage of understanding towards medications by comparing baseline values (during enrolment into DMTAC) with post values (at 4^{th} visit DMTAC for MMMAS and percentage of understanding, latest $HbA1_c$ nearest to 4^{th} visit).

The sample size calculation was performed using 'Power and Sample Size Calculations for Studies Involving Linear Regression' (Dupont and Plummer 1998). The obtained data were analysed using the paired t-test, IBM SPSS Statistics Version 21.0 (USA) software. A sample size of 56 was needed to obtain statistical significance in this study.

RESULTS

Fifty six patients who completed four visits in DMTAC programme counselling sessions between January 2013 and April 2014 were recruited as participants in this study. Table 1 shows the demographics and medication regimens of the 56 patients. Twenty seven patients (48.22%) out of the 56 patients recruited were within the body mass index (BMI) range of overweight (25.0–29.9 kg/m^2), and 18 (32.14%) of the patients were obese (BMI >30 kg/m^2). Nine (16.07%) patients were on oral hypoglycaemic agent, 45 (80.36%) patients were on dual combination therapy (OHA and insulin) and 2 (3.57%) patients were on an insulin regimen only.

Figure 1 shows that pharmacists performed a total of 80 interventions in this study; the majority of the interventions (40 [50%]) were dosage changes, particularly insulin dosage adjustments. Twenty (24%) of the interventions were changes in insulin regimens.

Table 1: Patient demographics and medication regimens.

Demographics	**No. of patients (%) N = 56**
Age	54.75 (SD = 8.174)
Gender	
Male	25 (44.64)
Female	31 (55.36)
Ethnicity	
Malay	32 (57.14)
Chinese	12 (21.43)
Indian	12 (21.43)
Body mass index (BMI)	
18.5–24.9 (normal)	11 (19.64)
25.0–29.9 (overweight)	27 (48.22)
>30 (obese)	18 (32.14)
Type of regimens	
Oral hypoglycaemic agent (OHA)	9 (16.07)
Oral hypoglycaemic agent (OHA) + insulin	45 (80.36)
Insulin only	2 (3.57)

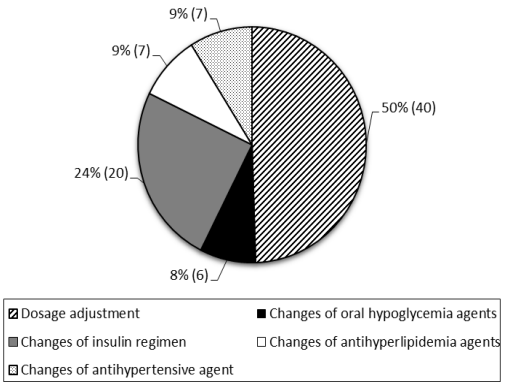

Fig. 1: Interventions performed by DMTAC pharmacist.

Forty three (77%) out of 56 patients achieved a reduction in $HbA1_c$ after completing 4 sessions of the DMTAC programme. Among the patients with improved $HbA1_c$, 28 (65%) had achieved at least a 1.0% drop in the $HbA1_c$ (Fig. 2).

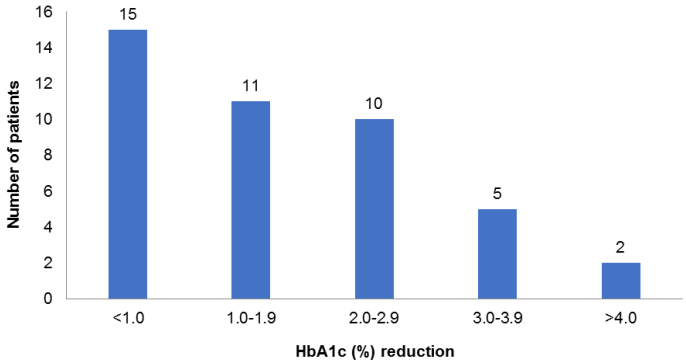

Fig. 2: Percentage of patients with specified reduction in glycosylated haemoglobin.

The mean $HbA1_c$ at baseline and post-4th DMTAC session data showed a statistically significant reduction of 1.0% ($p<0.001$, 95% CI 0.55, 1.46). We observed that the mean $HbA1_c$ after four DMTAC sessions was lower than at baseline [10.7% (1.51) compared with 9.7% (1.75)]. The mean medication understanding score for the group who had undergone 4 DMTAC sessions was 97.6% (7.32), which was significantly higher than the score at baseline (92.2% (13.61) ($p=0.005$, 95% CI 1.67, 8.98)). The mean MMMAS of the post-4th DMTAC session group was 7.4 (1.19), which was significantly higher than the baseline of 6.5 (2.33) ($p=0.001$, 95% CI 0.38, 1.36) (Table 2).

Table 2: Changes in DMTAC patients' $HbA1_c$, medication understanding and MMMAS at baseline and post-4th DMTAC session.

Outcome measure	Mean (SD)		Mean difference (SD)	(95% CI)	*p*-value*
	Pre-intervention	Post-intervention			
$HbA1_c$ (%)	10.7 (1.51)	9.7 (1.75)	1.0 (1.70)	(0.55, 1.46)	<0.001
Medication understanding (%)	92.2 (13.61)	97.6 (7.32)	5.3 (13.63)	(1.67, 8.97)	0.005
Medication adherence (MMMAS)	6.5 (2.33)	7.4 (1.19)	0.9 (1.84)	(0.38, 1.36)	0.001

DISCUSSION

Diabetes education plays a crucial role in managing diabetes and reducing the risk of common diabetes-related problems. Comprehensive diabetes education has been shown to be effective in improving disease outcomes (Iyer *et al.* 2010). The proper control of blood glucose is dependent on the patient's adherence to medications, lifestyle modifications, frequent monitoring of blood glucose, and proper education and counselling of the patients by healthcare professionals. The pharmacist's role in caring for diabetic patients has widely expanded because of the rapid expansion of available therapeutic agents in the management of diabetes. Patient counselling by pharmacists focuses on providing information to the patients about the disease, medications, and lifestyle modifications. These counselling sessions have been shown to improve therapeutic outcomes (Palaian, Chhetri and Prabhu 2004).

The findings of this study showed that the pharmacist-managed DMTAC programme significantly improved patients' $HbA1_c$, medication understanding, and adherence towards medications. In this study, the results showed a 1.0% of $HbA1_c$ reduction in comparison between pre- and post-4th DMTAC session data. The results of this study are comparable to another retrospective study which conducted by Lim and Lim (2010) that showed a mean $HbA1_c$ reduction of 1.73% after 8 sessions of a DMTAC programme (Lim and Lim 2010). Because there were no changes in the DMTAC module since the study by Lim and Lim (2010), the higher reduction in the $HbA1_c$ shown by Lim and Lim (2010) study could be because of the higher number of visits attended by the DMTAC patients. A similar pharmacist-led diabetic clinic in Australia showed a significant 0.9% reduction in $HbA1_c$ after a 6 months follow-up period (Krass *et al.* 2006). Patients who attended a pharmacist-managed diabetic clinic in Thailand showed a reduction of 0.8% in $HbA1_c$ levels and improvements in medication adherence level after 8 months of follow-up (Phumipamoma *et al.* 2008). A meta-analysis of data from 2,247 patients in 16 studies found a significant reduction in the $HbA1_c$ in the pharmacists' intervention group ($1.00\pm0.28\%$; $p<0.001$) (Machado *et al*. 2007).

According to a The United Kingdom Prospective Diabetes Study (UKPDS) study, the clinical implications for every 1.0% decrease in $HbA1_c$ values are tremendous because every 1.0% reduction in the $HbA1_c$ is associated with a relative risk reduction of 21.0% for any diabetes-related endpoint, 21.0% for diabetes-related deaths, 14.0% for myocardial infarction, and 37.0% for microvascular complications (Rozenfeld *et al.* 2008; Stratton *et al.* 2000). This study revealed that 50% of the pharmacist-managed patients have at least a 1.0% $HbA1_c$ reduction after 4 follow-up sessions. Therefore, the DMTAC programme in government health clinics in KL and Putrajaya indirectly improved the patients' microvascular endpoints, resulting in a better quality of life.

Pharmacists are equipped with specific training in pharmacology and medication management, and they play vital roles in undertaking interventions in T2DM patients (Donovan, Byrne and Sahm 2011). Many T2DM patients have complex dosing regimens consisting of long lists of medications. Therefore, pharmacists are the ideal healthcare professionals to educate the patients about their medications and improving their disease knowledge. Medication understanding was improved with pharmacist-managed diabetic programmes, and the comparison between the pre- and post-4th DMTAC session result was statistically significant. A related study on medication understanding by Nnaemeka and Kingsley (2012) showed that 72% of subjects knew the indication, dose, and frequency of their anti-diabetic medications (Nnaemeka and Kingsley 2012).

The pharmacist-managed diabetic patients showed significant improvements in their medication adherence levels, which are similar to the results of Lim and Lim (2010). Vivian and Leung (2003) demonstrated that the issues with compliance include patient demographics, regimen complexity, dosage frequency, adverse effects, polypharmacy, and hectic lifestyle. It was also important for diabetic patients to be familiar with their disease condition and medication regimen to enhance their medication compliance level (Shillinger *et al.* 2002). One significant role of the pharmacists in the DMTAC programmes was to improve patients' medication compliance by identifying possible causes of non-compliance and suggesting treatment modifications to the physicians (Shillinger *et al.* 2002). According to Vivian and Leung (2003), the mean±S.D. compliance rate improved from 41.3±25.6% at baseline to 97.8±8.9% at the end of the study ($p<0.005$) after 12 months. Several studies, such as the studies by Farsaei *et al.* (2011) and Grant *et al.* (2007) also revealed that medication adherence was significantly associated with better clinical outcomes.

One of the limitations of this study was that no control group was used; therefore, there were no direct comparisons between normal diabetic patients going to physicians and diabetic patients enrolled into DMTAC programmes. We suggest that a prospective

study with a control group be conducted in the future. Second, although DMTAC pharmacists undergo standardised module training before the DMTAC programme, the absence of a validated standardised tool or questionnaire for medication understanding assessment could lead to variance in the interpretations and scores among the DMTAC pharmacists in different health clinics. We suggest the DMTAC committee investigate this area.

CONCLUSION

The DMTAC programme demonstrates improvements in glycaemic control, medication understanding, and adherence level among T2DM patients by involving pharmacists in multidisciplinary teams in the outpatient clinics.

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