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 study aim is to determine the impact of pharmacist involvement in DMTAC programme on patients’ glycaemic control in 14 government health clinics in Kuala Lumpur and Putrajaya. Data was collected through multi-centred retrospective study which included DMTAC patients’ demographics, medication regimens, HbA1c levels, Modified Morisky Medication Adherence Scale (MMMAS) and percentage of understanding towards their medications were retrieved and reviewed from their DMTAC booklets. Data obtained was analysed using SPSS V.21. 56 patients were involved in this study. The mean HbA1c reduction (SD) of 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 post-intervention group was 97.6% (7.32) which was significantly higher than pre-intervention group 92.2% (13.61) (p=0.005). The mean MMMAS of post-intervention group was 7.4 (1.19) which was significantly higher than pre-intervention group 6.5 (2.33) (p=0.001). This study demonstrates an improvement in glycaemic control, medication understanding and adherence level among T2DM patients who were enrolled in pharmacist–managed DMTAC programme.
**Keywords:** Diabetes, Diabetes Medication Adherence Therapy Clinic (DMTAC), Endocrine, Pharmacist, HbA1c, Medication adherence, Medication understanding

**INTRODUCTION**

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

HbA1c, a form of glycosylated haemoglobin which is used to measure the patients’ glycaemic control over the past three months, is one of the clinical outcomes used as guidance to determine patients’ medication adherence level, understanding of their medications and to adjust diabetes medication doses. The Malaysian Clinical Practice Guideline recommends that the optimum level for HbA1c is less than 6.5% for type 2 diabetes mellitus (T2DM) patients (Clinical Practice Guidelines: Management of Type 2 Diabetes Mellitus, 4th edition, Ministry of Health Malaysia, 2009) Mayberry and Osborn, (2012) and Rozenfeld et al., (2008) have shown that better adherence towards medications improves glycaemic control and HbA1c levels among patients with T2DM. Nevertheless, improving patients’ medication adherence is the main challenge in healthcare setting.

Thus, in order to improve glycaemic control, Diabetes Medication Therapy Adherence Clinic (DMTAC) has been set up in Malaysia government healthcare facilities starting in 2006 with the aim to assist diabetic patients in improving their medication adherence level and glycaemic control (Lim PC and Lim K, 2010). In this ambulatory care service, pharmacists will collaborate with physicians in providing the services. Patients with poor glycaemic control are enrolled into DMTAC and will undergo follow up counselling sessions for a minimum of four visits. During every visit, they will receive medication adherence assessment via 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 (Lim PC and Lim K, 2010; Protocol medication therapy adherence clinic: diabetes, Pharmaceutical Services Division Ministry of Health, Malaysia 2010; Morisky et al., 2008). Glycaemic clinical outcomes including HbA1c, fasting blood sugar and random blood sugar will be monitored (Lim PC and Lim K, 2010).

A non-randomized prospective study conducted by Cioffi ST et al., (2004) in 70 Veterans Affairs patients which used a model similar to DMTAC found that after 9 to 12 months of participation, HbA1c, systolic and diastolic blood pressure, total cholesterol, LDL-c, triglycerides and level of microalbuminuria significantly decreased. A systematic review done by Machado et al., (2007) found that the meta-analysis of data from 2247 patients in 16 studies showed that the HbA1c levels significantly reduced in the pharmacists’ intervention group compared to control group. Pharmacists’ interventions further reduced HbA1c values over control (Machado et al., 2007). These reviews further proved that pharmacists’ intervention is important in improving patients’ glycaemic control.

In Malaysia, the effectiveness of DMTAC in improving patients’ glycaemic control is still debatable as related data is still limited. Although Lim et al’s study proved that DMTAC was effective in improving patients’ outcomes, his study was done in a hospital setting and is the only study of its kind in Malaysia. However, several studies have shown that by providing such clinical pharmacy service to the diabetes patients, the improvement of HbA1c, fasting blood glucose level, medication compliance and understanding of medication of diabetes patients can be achieved. Hence, this study would be able to determine the impact of pharmacist’s involvement in DMTAC programme on patients’ glycaemic control via monitoring of several significant parameters, including HbA1c level, MMMAS and percentage of medication understanding, amongst the government health clinic patient population, whose demographics may differ from that of a tertiary hospital setting in Lim et al’s study.

The aim of this study ultimately is to determine patients’ glycaemic control, understanding towards their medication and medication adherence in patients with T2DM who had enrolled into DMTAC programme, which is available in government health clinics in Kuala Lumpur and Putrajaya, to evaluate the impact of pharmacist-managed DMTAC programme amongst the government health clinics in Kuala Lumpur and Putrajaya and to analyse the retrospective data that is available in our current DMTAC database in order to observe the DMTAC patients’ performance in our health clinics.
METHODS

A retrospective and multi-centred study of the Diabetes Medication Therapy Adherence Clinic (DMTAC) programme was conducted in government health clinics, Kuala Lumpur and Putrajaya. Patients with T2DM from government health clinics in Jabatan Kesihatan Wilayah Persekutuan Kuala Lumpur & Putrajaya (JKWPKLP) who were enrolled into the DMTAC programme have been 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 above who had HbA1c levels more than 8%, and had completed at least four 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 patients’ demographics, medication regimens, and laboratory parameters including HbA1c levels. Records regarding patients’ adherence using MMMAS and assessment of patients’ understanding towards their medications were included. For medication understanding assessment, 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. Furthermore, interventions done by pharmacist with prior agreement by doctors were also included in the data to review the impact of pharmacists’ interventions on patients’ glycaemic control.

The primary outcome was to determine the mean difference in HbA1c level, MMMAS and percentage of understanding towards medications by comparing baseline values (during enrolment into DMTAC) with post values (at 4th visit DMTAC for MMMAS and percentage of understanding, latest HbA1c nearest to 4th visit).

Sample size calculation was done using ‘Power and Sample Size Calculations for Studies Involving Linear Regression’ (Dumont and Plummer, 1998). Data obtained was analysed using paired t-
test, SPSS Version 21 software. The sample size of 56 was needed to obtain a statistical significance for this study.

RESULTS

Within January 2013 and April 2014, 56 patients who have completed four visits in DMTAC programme counselling sessions were recruited as participants in this study. Table 1 showed the demographics and medication regimens of the 56 patients. Twenty seven patients (48.2%) out of 56 patients recruited were within the body mass index (BMI) range of overweight (25-29.9kg/m²) while 18 (32.1%) of patients were obese (BMI > 30kg/m²). Overall, 9 (16.1%) patients were on oral hypoglycaemic agent, 45 (80.4%) patients on dual combination therapy (OHA & insulin) and only 2 (3.6%) patients on insulin regimen.

Table 1: Patient demographics and medication regimens.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>No. of Patients (%) N=56</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>54.75 (SD= 8.174)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>25 (44.64)</td>
</tr>
<tr>
<td>Female</td>
<td>31 (55.36)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Malay</td>
<td>32 (57.14)</td>
</tr>
<tr>
<td>Chinese</td>
<td>12 (21.43)</td>
</tr>
<tr>
<td>Indian</td>
<td>12 (21.43)</td>
</tr>
<tr>
<td>Body Mass Index (BMI)</td>
<td></td>
</tr>
<tr>
<td>18.5-24.9 (Normal)</td>
<td>11 (19.64)</td>
</tr>
<tr>
<td>25-29.9 (Overweight)</td>
<td>27 (48.22)</td>
</tr>
<tr>
<td>&gt;30 (Obese)</td>
<td>18 (32.14)</td>
</tr>
<tr>
<td>Type of Regimens</td>
<td></td>
</tr>
<tr>
<td>Oral hypoglycaemic agent (OHA)</td>
<td>9 (16.07)</td>
</tr>
<tr>
<td>Oral hypoglycaemic agent (OHA) &amp; Insulin</td>
<td>45 (80.4)</td>
</tr>
<tr>
<td>Insulin only</td>
<td>2 (3.57)</td>
</tr>
</tbody>
</table>
Figure 1 showed that pharmacists made a total of 80 interventions in this study, with majority of the interventions, 40 (50%), were made on dosage changes, particularly on insulin dosage adjustment. 20 (24%) of the interventions were made on changes in insulin regimens.

Figure 2: Percentage of patients with specified reduction glycosylated haemoglobin.
Forty three (77%) out of 56 patients had achieved reduction in HbA1c after completing four sessions of DMTAC programme. Among the group of patients with improvement of HbA1c, 28 patients (65%) had achieved at least 1.0% drop in HbA1c (Figure 2).

Table 2: Changes in DMTAC patients' HbA1c, medication understanding and MMMAS at baseline and post-4th DMTAC session data.

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Mean (SD)</th>
<th>Mean Difference (SD)</th>
<th>(95% CI)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-intervention</td>
<td>Post-intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBA1c (%)</td>
<td>10.7 (1.51)</td>
<td>9.7 (1.75)</td>
<td>1.0 (1.70)</td>
<td>(0.55, 1.46)</td>
</tr>
<tr>
<td>Medication Understanding (%)</td>
<td>92.2 (13.61)</td>
<td>97.6 (7.32)</td>
<td>5.3 (13.63)</td>
<td>(1.67, 8.97)</td>
</tr>
<tr>
<td>Medication Adherence (MMMAS)</td>
<td>6.5 (2.33)</td>
<td>7.4 (1.19)</td>
<td>0.9 (1.84)</td>
<td>(0.38, 1.36)</td>
</tr>
</tbody>
</table>

The mean HbA1c 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 HbA1c after four DMTAC sessions was lower than the data at baseline [10.7% (1.51) compared to 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 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).

DISCUSSION

Diabetes education plays a crucial role in managing diabetes and reducing the risk for common diabetes-related problems. Comprehensive diabetes education has also been shown to be effective in improving disease outcomes (Lyer 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 as well as proper education, and counselling of the patients by healthcare professionals. The pharmacist's role in caring for
diabetic patients has widely expanded due to rapid expansion of available therapeutic agents in management of diabetes. Patient counselling by pharmacists focuses on providing information to the patients regarding the disease, medications, and lifestyle modifications. Such counselling sessions has been shown to improve therapeutic outcomes (Palaian et al., 2004).

The findings of this study showed that the pharmacist-managed DMTAC programme significantly improved patients’ HbA1c, medications understanding and adherence towards medications. In this study, the result showed 1.0% of HbA1c reduction in comparison between pre- and post-4th DMTAC session data. This study result was comparable to another retrospective study which was conducted by Lim et al., (2010) with a mean HbA1c reduction of 1.73% after eight sessions of DMTAC programme (Lim PC and Lim K, 2010). As there were no changes in the DMTAC module since Lim et al’s study, the higher reduction in HbA1c shown by Lim PC and Lim K (2010), study could be due to the higher number of visits attended by DMTAC patients. A similar pharmacist-led diabetic clinic in Australia also showed a significant 0.9% reduction in HbA1c after a six-month follow-up session (Krass et al., 2006). Patients who underwent pharmacist-managed diabetic clinic in Thailand showed a reduction of 0.8% in HbA1c and improvement in medication adherence level after eight months of follow-up (Phumipamama, 2008). Meta-analysis of data from 2247 patients in 16 studies found a significant reduction in HbA1c in the pharmacists’ intervention group (1.00 ± 0.28%; p < 0.001) (Machado et al., 2008).

According to UKPDS study, the clinical implications for every 1.0% decrease in HbA1c values are tremendous, as every 1.0% reduction of HbA1c 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 1.0% of HbA1c reduction after four follow-up sessions. Hence, the DMTAC programme in government health clinic, in KL and Putrajaya has indirectly improved on the patients’ microvascular endpoint, resulting in better quality of life.

Pharmacists are equipped with specific training in pharmacology and medication management and thus, they play vital role in undertaking interventions in T2DM patients (Donovan, Byrne and Sahm, 2011). It was known that many T2DM patients have complex dosing regimen consisting of long-list medications. Hence, pharmacists are the ideal healthcare professionals to educate the patients about their medications besides improving their disease knowledge. The medication understanding has been
improved with pharmacist-managed diabetic programme and the comparison between pre- and post-4th DMTAC session result was statistically significant. A related study on medication understanding by Nnaemeka et al. (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 improvement in their medication adherence level, which is similar with results shown by Lim et al., (2010). Vivian et al., (2003) revealed that the issues with compliance include patient demographics, regimen complexity, dosage frequency, adverse effects, polypharmacy as well as hectic lifestyle. It was also imperative for the diabetic patients to be familiar with their disease condition and medication regimen which would in turn enhance their medication compliance level (Shillinger et al., 2002). One of the significant roles of the pharmacist in DMTAC programme 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 et al., (2003), the mean ± S.D. compliance rate was 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 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 in this study was that, no control group was used leading to no direct comparisons between normal diabetic patients going through physicians and diabetic patients enrolled into DMTAC programme. Therefore, we suggest that a prospective study with control group could be conducted in the future. Secondly, although DMTAC pharmacists have undergone standardized module training before being involved in DMTAC programme, the absence of a validated standardized tool or questionnaire for medication understanding assessment could lead to variance in interpretations and scores among the DMTAC pharmacists in different health clinics. Hence, we propose the DMTAC committee to look into this area.
CONCLUSION

The DMTAC programme demonstrates an improvement 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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