

ORIGINAL ARTICLE

Drug Utilisation Evaluation Study on Patients with Diabetes Mellitus Among Rohingya Refugees in IMARET Mobile Clinic

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ABSTRACT

Introduction: Since 1978, Rohingya refugees have fled from their native nation, Myanmar to escape ethnic prosecution. They comprise of the Muslim minority ethnic group originating from the Rakhine state in Myanmar. In many host countries, they may have difficulty to access health care services. The Islamic Association of Malaysia (IMAM) Response and Relief Team (IMARET) have taken many initiatives to provide healthcare services to the refugees through their volunteer-led mobile clinics. Therefore, this study aims to evaluate the utilisation of drugs among type 2 diabetes mellitus (T2DM) patients visiting this clinic. **Methods:** This was a cross-sectional study among Rohingya refugees with T2DM that visited the IMARET mobile clinics from August until November 2017. Convenient sampling method was used. Data were collected through patient's interview, review of the patient's prescriptions and their HbA1c readings. **Results:** A total of 29 T2DM patients were included in this study. The majority were female (75.9%) and aged below 65 years old (75.9%). The most commonly prescribed anti-diabetic agent was metformin (72.2%), followed by glibenclamide (22.2%) and gliclazide (5.6%). Metformin as a monotherapy (31%) was the most frequent treatment prescribed. More patients had controlled T2DM (62.1%) compared to those with uncontrolled DM. We found 90.9% of patients who were treated according to the recommended DM guidelines achieved a good blood glucose control ($p=0.02$). **Conclusion:** In Rohingya refugees having T2DM who were treated in the IMARET mobile clinic, the percentage having good control DM status is higher in those whose treatment regimen adheres to the clinical practice guidelines.

Keywords: Drug utilisation evaluation, Diabetic patients, Diabetes mellitus, Rohingya refugees, Mobile clinic

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INTRODUCTION

The Rohingyas are a Muslim ethnic minority group originating from the Rakhine state in Myanmar, which borders with Bangladesh on the north and the Bay of Bengal on the west. In 1978, ethnic prosecution forced more than 200 000 Rohingyas to flee to the neighbouring state of Bangladesh. By 2012, the conflict reached its climax with frequent occurrence of violent clashes between the Rohingya and Rakhine population causing another 140 000 Rohingya to flee to internally displaced person (IDP) camps. Since then, the Rohingyas have also fled to other Asian countries, namely Bangladesh,

Thailand and Malaysia (1). As of January 2017, 56 135 Rohingyas have been registered with United Nations High Commissioner for Refugees (UNHCR) in Malaysia. The Rohingyas are at risk of poor health and nutritional status due to their lack of education and employment opportunities as well as access to health care services. The barriers in accessing health care services are mainly contributed by high medical costs and also major problem in terms of language barrier (2).

Type 2 diabetes mellitus (T2DM) remains a major public health concern worldwide and is associated with severe microvascular and macrovascular complications. Based on IMARET's medical records over the previous years, there were 56 cases of DM that were detected among the 1402 Rohingya refugee patients that visited the mobile clinic from the period of September 2015 to December 2016. Due to the many problems that directly inhibit

access to quality healthcare services, refugees therefore become hesitant to seek the required medical help, hence they are at higher risk of developing the severe complications from their medical conditions (2). Hence, this may lead to more severe diabetic complications in this community.

IMAM Response & Relief Team better, known as IMARET is a chapter by the Islamic Medical Association of Malaysia (IMAM). IMARET's main aim is to provide high quality healthcare services and promotional activities to those in need of these essential services. Among the activities done by IMARET is providing emergency health care relief to those involved in natural or man-made disaster such as the recent Malaysian East Coast flood relief and Sulawesi Tsunami relief. IMARET not only reaches out to those in need in Malaysia but are also active internationally by involvement in major volunteering activities such as in Cox Bazaar which is located in Bangladesh itself, primarily to assist the Rohingya refugee community there through health check-ups. IMARET is also involved in running many mobile clinics for other marginalised communities in Malaysia such as the Orang Asli and Bajau Laut communities. This is in addition to the mobile clinics that are dedicated to the Rohingya refugees in Malaysia.

IMARET members include both Muslims and non-Muslims who are either healthcare or healthcare related professionals and students. The mobile clinics are held once every fortnight or month, depending the number of personnels available to man the clinic. IMARET will prepare the equipments, medications, and also organise the volunteers' pools to both set up and run the clinic which is usually held on Sundays.

The clinics are usually set up at places that are easily accessible to the Rohingya community in Malaysia. The leaders of the community will be advised on the location the clinics beforehand and will then be tasked with spreading the word among their social contacts. Funding of these clinics are by generous donations from corporate sponsors and the general public. All medications are kept in a warehouse, carefully supervised by IMARET.

Drug Utilisation Evaluation (DUE) also known as drug utilisation review (DUR) or medication utilisation evaluation (MUE), is defined as an authorised, structured, and ongoing review of healthcare providers' prescribing pattern, pharmacists' dispensing pattern and patients' use of medication. This is basically a broad evaluation of patient's medication and prescription information before, during and after dispensing. This is done to ensure that accurate decision making steps and desired patient outcomes are achieved (3). Prior to this study, no evaluation of the treatment prescribed to refugees with T2DM were done. Specifically, for this IMARET mobile clinic, DUE/MUE is done for the following purposes: 1) for procurement of pharmaceutical drugs 2) to evaluate

the efficiency of administrative process of the day to day clinic operation 3) as part of an internal audit for improving the service delivery to the refugees and 4) to report of usage of fund to the stakeholders / donors.

This study was conducted to evaluate the utilisation of drugs among Rohingya refugees with T2DM, characterised by the drug prescribing pattern, appropriateness of anti-diabetic regimens prescribed, and an analysis of clinical and sociodemographic profile of the refugees with diabetes.

MATERIALS AND METHODS

This was a cross-sectional study conducted among the Rohingya refugees who presented to the mobile clinics with T2DM from the month of August until November 2017. IMARET mobile clinics are strategically located at the districts of Selayang, Seri Kembangan and Ampang in Malaysia. Data was collected via patient interview, review of their prescriptions, and by conducting the HbA1c test. Convenient sampling method was used in this study as the sample for this study depends on how many T2DM patients visited the mobile clinic during the period of study.

Patients attending the clinic will initially be registered at the registration counter, where they will be screened for eligibility to participate in the study. The inclusion criteria are patients that have evidence of previously diagnosed T2DM, such as having a referral letter from another clinic coupled with anti-diabetic drug(s) prescription or through diagnosis made during previous IMARET mobile clinics. We excluded those that are below 18 years old, the newly diagnosed and those that refuse testing for capillary blood glucose and HbA1c test for determining the latest blood glucose level. Once they have fulfilled the inclusion criteria, they will be recruited into the study and briefed on the major objectives and steps involved in the study which also would include analysis of their blood glucose control. The blood tests are usually done as soon as the patient is registered, and when the results are available, they will then proceed to have consultation with the volunteer doctor. The doctor will then manage the patient accordingly. The decision to treat and manage the individual patient is based on the clinical evaluation and expertise of the treating doctor. The patient will then proceed to the dispensary to refill their prescription. Follow ups will normally be arranged in a month due to the limitation of medication supply, unless there are no clinic organised due to unforeseen circumstances, which include raids done by the enforcement team such as those from immigration officers.

The interview of the participants were usually done by trained researchers while the participants await their blood results. The researchers will use the help of trained translators to ask the relevant questions in those who

have problems communicating in Malay or English. The translators are trained Rohingya refugees who had basic education in the Pelangi Kasih School conducted by the non-governmental organisation, Human Aid, where they were also taught to speak both these languages.

The patients' socio-demographic data were analysed along with their HbA1c and glucometer readings. Based on the socio demographic and clinical data, patient's target HbA1c were determined based on the Malaysian T2DM Clinical Practice Guideline (CPG) 2015 (12). This guideline was adapted from the position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) in 2012 (7, 12). This committee incorporated several factors that determined the specific goals for blood glucose control such as the patient's age, time since diagnosis, and the presence of comorbidities (10). Besides that, the current treatment regimen that the patients were receiving, were also compared to the one detailed in the Malaysian CPG. According to this important guideline, the blood glucose level and/or the HbA1c level of the patient will determine the type of treatment that they should received.

Tools

1. A structured data collection form was designed to capture the data. The data collection form was developed by the researchers based on the Malaysian Clinical Practice Guidelines on Management of Type 2 DM 2015 which were as the main guide. The data collection form consists of four main sections which are:

Section 1: Demographic details

Section 2: Clinical background that includes measurements of body mass index (BMI), blood pressure and blood glucose levels. The random or fasting capillary blood glucose measurements are taken as normal flow of diabetic clinic, but the results are not analysed in this study.

Section 3: Type of therapy received, and the anti-diabetic agent prescribed

Section 4: Documentation of DM control status based on the HbA1c target

2. Point of care HbA1c device

This machine analyses patient's HbA1c level via finger prick testing and has been approved by the US Food and Drug Association as a validated HbA1c monitoring device. It has been shown to have good specificity and sensitivity. However, compared to laboratory results, it has been shown to be less accurate in reporting the HbA1c level (11).

Data collected were analysed using Statistical Package for the Social Sciences (SPSS) software version 23.0. The socio demographic data, clinical characteristics of the participants and analysis of their prescriptions were reported using descriptive statistics. The association

between the treatment regimen prescribed according to the local guidelines with the overall diabetic control and the correlations between BMI with age and HbA1c levels were determined using the Fisher's exact test and Pearson's correlation tests, respectively. The level of statistical significance was set at $p < 0.05$.

Ethical approval was obtained from Cyberjaya University College of Medical Sciences (CUCMS) Research Ethics Review Committee (CRERC)[reference number: CUCMS/CRERC/FR/013].

RESULTS

Demographic Data & Clinical characteristics

Table 1 shows the demographic data and clinical characteristics of the participants. A total of 39 patients who attended the IMARET mobile clinic from August until November were screened for inclusion and exclusion criteria for recruitment into this study. However, only 29 patients were included in this study and the remaining 10 was excluded due to not meeting the criteria outlined. The majority of the patients with T2DM at the mobile clinic were aged below 65 (22, 75.9%) with a mean age of 50.9 ± 12.2 years. Most of the patients were female (22, 75.9%). The majority of the T2DM patients were obese (17, 58.6%) with only four participants (13.8%) being of normal weight.

Table 1: Demographic Data and Clinical Characteristics of Patients

Characteristic	Frequency (%) (N = 29)	Range	Mean (SD)
Age		(32-75)	50.9 (12.2)
Below 65 years old	22 (75.9)		
65 years and above	7 (24.1)		
Gender			
Male	7 (24.1)		
Female	22 (75.9)		
HbA1c control (%)		(4.8 - 10.4)	7.4 (1.7)
< 6.5%	9 (31)		
6.5 - < 7.5%	7 (24.1)		
7.5 - < 8.5%	3 (10.3)		
8.5 - < 10%	7 (24.1)		
>10%	3 (10.3)		
Blood Pressure (mmHg)			
Systolic		(102- 189)	139.2 (21.7)
Diastolic		(37- 116)	86.3 (15.9)
BMI (kg/m²)		(17.9-43.3)	27.5 (6.1)
Underweight (< 18.5)	2 (6.9)		
Normal (18.5 - 22.9)	4 (13.8)		
Overweight (23- 27.4)	6 (20.7)		
Obese (≥ 27.5)	17(58.6)		

Prescribing patterns of T2DM patients in IMARET Mobile Clinic

The anti-diabetic agents prescribed in this clinic are shown in Table II. Metformin was the most frequently prescribed oral anti-diabetic drug and is used either as a monotherapy or as a combination therapy. The majority of the patients were on lifestyle therapy (15, 51.7%) as compared to 14 patients that were either on monotherapy or combination therapy involving biguanides (metformin) or sulphonylureas (glibenclamide, gliclazide).

Table II: Anti-diabetic Agents' Prescription Patterns

Treatment	Frequency (%) (N=29)
No treatment (lifestyle approach)	15 (51.7)
Monotherapy	
Metformin	9 (31)
Glibenclamide	1 (3.4)
Combination	
Metformin + glibenclamide	3 (10.3)
Metformin + gliclazide	1 (3.4)

Table III shows the type of therapy the participants are receiving based on the glycemic control of the participant. Patients who have good control of their HbA1c levels were mostly on diet modification (7, 24.1%), while for all 3 patients with HbA1c of >10%, they were only on a single oral anti diabetic drug (OAD). The patients were later categorized according to the recommended target glycemic control based on their co-morbid medical conditions. Table IV illustrates the target HbA1c for each patient based on the Malaysian CPG T2DM guidelines 2015. Each patient has been categorised based on their sociodemographic and co morbidities data to their targeted HbA1c. Out of the 9 patients that had a target HbA1c level of 6.0-6.5, only 5 of them reached this target. The other 4 patients did not achieve this target glycemic control level. Overall, majority of the patients reached the target HbA1c levels (18, 68.1%). Table V shows the compliance to treatment recommendation by physicians based on patient's HbA1c levels. Only 44.8 % of the physicians followed the recommended prescription guidelines with none of them complying with the treatment guidelines when the HbA1c level exceeds 8.5%. Table VI shows the association between the treatment plan of T2DM patients in the mobile clinic with their diabetic control. This association was significant (p=0.02) with 92.3% of patients treated according to the recommendations and having a good glycemic control. Table VII shows the correlation between HbA1c control with age and BMI; however, both these correlations were not significant.

DISCUSSION

This study was done in a volunteer-based mobile clinic in which the main aim of this clinic was to help the Rohingya refugee community residing in Malaysia obtain quality medical care. The volunteers are mainly

Table III: Type of Therapy Prescribed Based on Glycemic Control

Glycemic control (%)	Type of therapy (N = 29)		
	No treatment (lifestyle approach)	OAD monotherapy	Dual combination therapy
<6.5	7 (24.1)	2 (6.9)	0 (0)
6.5- <7.5	4 (13.8)	3 (10.3)	0 (0)
7.5- <8.5	1 (3.4)	1 (3.4)	1 (3.4)
8.5- 10	3 (10.3)	1 (3.4)	3 (10.3)
>10	0 (0)	3 (10.3)	0 (0)

OAD= oral anti diabetic

Table IV: Target Glycaemic Control based on the Malaysian CPG Recommendation

Target HbA1c (%)	DM control (N= 29)		
	yes	no	Total
	Frequency (%)	Frequency (%)	Frequency (%)
6.0-6.5	5 (17.2)	4 (13.8)	9 (31.0)
6.6-7.0	5 (17.2)	4 (13.8)	9 (31.0)
7.1-8.0	8 (20.7)	3 (17.2)	11 (37.9)
Total	18 (62.1)	11 (37.9)	

CPG= Clinical Practice guidelines

Table V: Prescribing Habits in the IMARET Mobile Clinic Compared to the Malaysian CPG

HbA1c (%)	Treatment recommendations	Prescription following recommendation (N= 29)	
		Yes (%)	No (%)
< 6.5	No treatment given (lifestyle approach)	9 (31.0)	0 (0)
6.5-<7.5	OAD monotherapy	3 (10.3)	4 (13.8)
7.5- <8.5	Dual combination therapy	1 (3.4)	2 (6.9)
8.5- 10	Triple combination therapy	0 (0)	7 (24.1)
>10.0	Combination therapy + insulin	0 (0)	3 (10.3)
	Total	13 (44.8)	16 (55.2)

CPG= Clinical Practice guidelines, \$- patients were already started on therapy and as per CPG guidelines, if HbA1c < 6.5 to continue treatment

Table VI: Association of Treatment According to the Malaysian CPG with Diabetic Control[#]

Adherence to guidelines	Frequency (N= 29)	DM control (N= 29)		X ² (df)	P value [#]
		Controlled	Uncontrolled		
Yes	13	12 (92.3)	1 (7.7)	13.14 (1)	0.002*
No	16	4 (25)	12 (75)		

CPG= Clinical Practice guidelines, #=Fisher exact test

Table VII: Correlation Between HbA1 Control, Age and BMI

	HbA1c control (%)	
	Correlation coefficient, r	P value
Age	-0.117	0.546
BMI	0.250	0.190

*Pearson's correlation test

healthcare professionals and students, and the funding for the clinic needs are mainly by donation. Donations include in the form of the medications that are supplied free of charge to the clinic, or when the volunteers purchased the drug stock according to the needs and drug supply level of the clinic.

A total of 29 patients were included in this study. The majority of the T2DM patients at the mobile clinic are females. This is similar to a study among adults in Vietnam that showed that women are more likely to have T2DM than men (4). Another study done among refugees also stated that majority of patients with chronic disease are females because many of their male counterparts were killed during the violence clashes as described earlier(5). The majority of the patients with DM at the mobile clinic are aged below 65 years old. This concurs with another study done among Myanmar refugees that stated that the majority of them are young adults in the age group of 20-45 years old (6).

The majority of patients have HbA1c of less than 6.5%, that clearly indicates that the treatment provided at the clinic has helped to improve the glycaemic control among the refugees with T2DM. Rather unsurprisingly, we found that the majority of the T2DM patients were obese and overweight. This is also seen as a common phenomenon in both the refugee and non-refugee population as supported by a study done among refugee psychiatric patients that showed an increase in percentage of diabetes and hypertension with increasing BMI (5). Nevertheless, we found no significant correlation between patient's age and BMI and their HbA1c levels.

This study mainly looked at the drug prescribing pattern by the volunteer doctors and compared them to the local guidelines. Prior to 2018, when there were no official volunteers list, the volunteer recruitment was handled by appointed IMARET staff. Prior to holding the clinics, message on the need of volunteer doctors and healthcare professionals were shared via social media. There are at least two fully registered doctors in each clinic session, and the rest were support staffs. The qualifications of the doctors that volunteered for these clinics were verified by their annual practice certificate (APC) numbers. They were mainly medical officers working in government health facilities and are not necessarily practicing in the primary care level. Sometimes, specialists would also volunteer their service to this noble cause.

The treatment available are based on public and corporate funding. The oral hypoglycemic agents available are metformin 500mg, glibenclamide 5mg and gliclazide 80mg. The staff in charge will check that the medication supplies are sufficient prior to the clinic sessions. If not, it will be purchased with the donated funds. Sometimes, there are donation of certain types of medication such as metformin XR in which the IMARET

exco in charge of the clinic will screen first on its need and use in the clinic, and then decide whether to accept or decline this free supply. For example, insulin is not accepted due to storage and language barrier reasons. The patients will be prescribed whatever is available during their follow up. Patients are usually given follow up in a month regardless, as the medications are only given for a maximum of one month.

Metformin was the most frequently prescribed anti-diabetic agent at the mobile clinic. This was not unexpected as according to Malaysian CPG Management of T2DM, metformin would be the preferred choice as a first line therapy. Furthermore, if the use of metformin is not contraindicated, it is the preferred and a cost-effective agent when used as the initial drug therapy for T2DM (7). This study found that metformin use as a monotherapy and also in combination therapy were the most commonly prescribed treatment regimen which was also reflected in a previous study done in an outpatient care setting (8). However, the prescription of combined therapy involving metformin and gliclazide are more common in this study as opposed to the usual combination of metformin and glibenclamide, which is in contrast with a study done in an outpatient clinic setting in Nigeria (9). Understandably, the combination of metformin and gliclazide is more preferred as gliclazide causes less risk of hypoglycemia as compared to the older generation sulphonylureas such as glibenclamide (12).

Targets for each patients' HbA1c levels were individualised according to the patient's overall clinical profile based on the Malaysian CPG on the management of T2DM. Factors taken into consideration included the patient's co-morbidities, age, duration of illness and the risk of hypoglycemia (10, 12). We found that the percentage of patients in each target groups were similar which was around 30%. In terms of achieving the recommended glucose control, this study found that 37.9% of the patients did not achieve their target HbA1c level. It is also noted that a high 62.8% of the treatment prescribed were not adhering to the Malaysian type 2 diabetes mellitus CPG. One of the main reasons identified were because there were no insulin therapy available to be dispensed for the patients. The mobile clinic does not stock up insulin supply due to the extra measures needed to store, along with the cost implications, and also the problem of language barrier faced by the volunteers that may cause difficulties in educating the patients on correct insulin injection techniques. Another reason for patients not achieving the target glycemic levels is due to the lack of therapy intensification by the healthcare provider (i.e physician's inertia). An earlier study had suggested that one of the primary factors contributing to the failure of the patients with DM to achieve glycemic control is due to lack of appropriate intensification of medication therapy by the healthcare provider, which may also be the case in this study (14). The adherence

to the recommended treatment prescribed according to the CPG guidelines and DM control of patients in this study showed significant association ($p=0.02$). The patients who received treatment that followed the recommendations of the guidelines have a higher odd of having a good glycaemic control as compared to those who received treatment that did not adhere to the guidelines.

Nevertheless, there are also many other factors affecting the optimization of treatment among patients with T2DM and this has been studied in great detail in previous studies. Among the issues that are important and may affect the control of this condition is adherence to treatment, diabetic self-care, diabetic self-efficacy and social support (14-16). This is however, not within the scope of this study, mainly due to the limited time and the problem faced in term of language barrier.

There is not denying that they are many challenges in providing healthcare to refugees. These includes the lack of knowledge and access to basic health care in addition to the fear of risk of arrest and limited opportunity for education among this marginalized community (17,18). Because they are not Malaysian citizens, in order to receive medical care, they often need to pay for treatment. The cost of healthcare is a burden to them, and as most of them are unemployed, they are often unable to pay for the medical fees. Their refugee status prevents them from working legally, hence the vicious cycle continues. Although many agencies are providing financial aid to those with refugee status, the procedure of being registered legally under United Nations High Commissioner for Refugees (UNCHR) is a long and tedious process. This leaves many loopholes for the people of Rohingya origin in order to seek their basic human right for quality healthcare. There are many non-governmental organizations (NGO) that are taking steps to help these unfortunate community and among them is the setting up of mobile clinics similar to our study to help ease some of their burden. This includes the services provided by the UNCHR including registration and providence of UNCHR card which enables certain useful benefits such as rebate for the cost of health care at government health facilities (18). However, there is still a big number of refugees with health problems that are often left neglected. We hope that this article can raise awareness on this issue and therefore, more steps are taken towards the wellbeing of this marginalised group.

Steps that can be taken by medical NGO's such as IMARET includes among other, to continue doing their monitoring of treatment for refugees, and to educate the volunteer doctors on the proper management on chronic diseases such as T2DM. Other steps that can be taken is finding the right volunteers to run the clinics, especially those who are working in the primary care setting. This itself poses as a big challenge as IMARET cannot be too

choosy when it comes to manpower due to the lack of willing volunteers. Provision of a high-quality culture sensitive healthcare services to the refugees can be both fulfilling and challenging (17). To be able to provide this kind of services, primary care physicians should be the front liner as they are most of the time able to understand the physical and psycho-social problems faced by this special group of the population. This will in a way call for more training on refugees' healthcare needs including addressing issues of mental health (19). A study in Sweden among refugees revealed that the quality of health care provision to this group was similar as to non-refugees (20). However, what is most often desired by this marginalised group was provision of more information about their medical problem and a feeling of a sense of caring by the health professionals (20). Therefore, this reiterate the call for more training in this aspect of health services. Alas, a developed society's moral standard will be determined by how its most vulnerable citizens are treated (17). Also, equally important is the need to have a high index of suspicion to diagnose DM in those with atypical presentation such as lethargy and genital infection as to not missed out on this important diagnosis (21).

To our knowledge this is first study of its kind among Rohingya patients with T2DM in Malaysia. Nevertheless, we are aware of the limitations of this study in which is only a small group of patients were recruited due to the limited time of this study. This study was only done in the state of Selangor by a single NGO and may not reflect the findings of other similar populations elsewhere in Malaysia. We realise that this study only takes into consideration the prescribed medications and does not explore other issues such as patient's knowledge, adherence, diabetes self-care and self-efficacy. We would recommend a bigger, nationwide study involving more NGOs that provide the same services in order to get a larger pool of patients to confirm the findings of this study.

CONCLUSION

In Rohingya refugees with T2DM treated in the IMARET mobile clinics, the percentage of controlled DM status is higher in those that had their treatment regimen adhering to the clinical practice guidelines. Therefore, interventions should be offered according to the recommendations by the guidelines while considering all the limitations that are usually encountered at such mobile clinics. The treatment of DM offered to refugees in the IMARET mobile clinic still needs much improvement. More funds and support will go a long way to the improve the scope of services offered by this noble initiative.

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