



## Gycaemic Control and Treatment Profile amongst 20646 Adult Type 2 Diabetes Mellitus: A Descriptive Report

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### ABSTRACT

An audit of Diabetes Control and Management-Diabetes Registry Malaysia (ADCM-DRM) was started to monitor the provision of diabetes care in the country. A total of 20,646 patients were registered in the registry until 31<sup>st</sup> December 2008. This report set out to determine the Type 2 diabetes controls and treatment profiles of these cohorts of patients. This was a registry-based observational study conducted from May to December, 2008. An online standard case record form was available for site data providers to register their diabetic patients aged 18 years old and above annually. Demographic data, diabetes duration, treatment modalities, as well as various risk factors and diabetes complications were reported. Data were analyzed using Data Analysis and Statistical Software (Stata) version 9. A total of 81 centres, 6 of which were hospitals, participated in this registry until 31<sup>st</sup> December 2008, contributing a total of 20646 patients. A majority of them (99.2%) had Type 2 diabetes mellitus. The mean HbA1c was 8.0% (SD 2.10), with 30.1% and 17.9% of the patients who attained HbA1c < 7% and HbA1c < 6.5%, respectively. Metformin was prescribed more than sulfonylurea while only 11% had insulin. A review of the diabetic care policy and strategies in the primary health care clinics is needed to implement a more effective treatment of diabetes in this country.

**Keywords:** Primary care, Registries, Glycaemic control, Hypoglycaemic agents

#### Article history:

Received: 1 July 2011

Accepted: 29 February 2012

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### INTRODUCTION

The number of people with diabetes is expected to increase alarmingly in the coming decades. In 1985, an estimated 30 million people worldwide had diabetes; in 2000, a little over a decade later, the figure had risen to over 150 million. By 2030, the figure is

expected to rise to 439 million (International Diabetes Federation, 2009). The prevalence of diabetes mellitus in Malaysian adults aged 30 years old and above has doubled over the ten year period from 8.3% in 1996 to 14.9% in 2006 (National Health Morbidity Survey, 1996; Institute of Public Health, 2008). According to the International Diabetes Federation estimates for 2010 and 2030, Malaysia is among the top ten countries with the highest prevalence of diabetes mellitus (International Diabetes Federation, 2009).

Diabetes mellitus is one of the commonest chronic, non-communicable diseases which contribute to a high level of morbidity and mortality globally with its impacts coming not only from diabetes mellitus itself, but mainly arising from its complications such as coronary artery disease and chronic kidney disease (Garcia *et al.*, 1974; National Health Morbidity Survey, 1996; Lim *et al.* 2009). Studies have shown that with good glycaemic control and control of other concomitant cardiovascular risk factors, there would be delay in complications (The Diabetes Control and Complications Trial Research Group, 1993; UKPDS, 1998; Berl *et al.*, 2003; Sever *et al.*, 2005; Patel *et al.*, 2007; Action to Control Cardiovascular Risk in Diabetes Study Group, 2008; ADVANCE Collaborative Group, 2008). Findings from UKPDS showed that for every 1% reduction in HbA1c, there was 37% reduction in micro-vascular complications, about 40% reduction of all diabetic-related end-points, myocardial infarction and death in the metformin sub-group analysis (UKPDS, 1998). This protective effect of early intensive glycaemic control persisted into the following decade post study (Holman, 2008). However, the achievement of the control to the recommended target level is not satisfactory. Clinical audit is one of the measures which health care providers use to assess and monitor their care to the patients. By implementing changes to the shortfalls found, health care providers hope to improve on the quality of care to the patients and subsequently delay the complications.

Clinical audit is one of the measures which health care providers may use to assess and monitor their care to the patients (Costa, 2009). An online diabetes registry database called the "Audit of Diabetes Control and Management-Diabetes Registry Malaysia (ADCM-DRM)" was started in July 2008 as a pilot project in Negeri Sembilan (NS) (ADCM manual; CRC, Kuala Lumpur). The objectives of this online registry was to gather and monitor the provision of diabetes care; hence, to better inform outcomes of treatment, budget planning, health education for both the physician and patients as well as to increase awareness of the potential serious impact of this disease on the country (Stamler *et al.*, 1993; American Diabetes Association, 1998; American Diabetes Association, 2001). This registry was managed by a secretariat based at Clinical Research Centre, Hospital Kuala Lumpur. The main source data providers (SDP) were those from government health clinics and hospitals throughout NS, Selangor and Perak. This report set out to determine the Type 2 diabetes controls and treatment profiles as up to 31<sup>st</sup> December 2008.

## **MATERIALS AND METHODS**

This study was approved by the Medical Research Ethics Committee (MREC), Ministry of Health, Malaysia. ADCM-DRM database from July to 31<sup>st</sup> December 2008 was cleaned before the analyses were carried out. All public hospitals and health clinics were invited to participate as SDP. Participation was voluntary. An online standard case record form (CRF) was available

in the ADCM website for SDP to register their diabetic patients aged 18 years old and above annually. This was done by trained physicians and paramedics. Patients with T2D were defined as when their case record fulfilled all these criteria: (1) either documented diagnosis of diabetes mellitus according to World Health Organisation (WHO) criteria, or (2) those whose current treatment consisted of life-style modification, on oral anti-diabetics or insulin. The data captured include demography, diabetes duration, treatment modalities, as well as various risk factors and diabetes complications. Each of the selected SDP site administrators was given a password guarded access to the website in order to generate local data that was analysed by the secretariat. Data were analysed using STATA version 9. The detailed methodology of this project has been described elsewhere (Mastura *et al.*, 2008).

## RESULTS

A total of 81 centres, 6 of which were hospitals, participated in this registry until 31<sup>st</sup> December 2008, contributing a total of 20,646 patients. A majority of the patients (89.6%) were from Negeri Sembilan and most of the cases were Type 2 diabetes mellitus (T2D) (99.2%). In more specific, 57.2% were females, while Malays made up 57.1%, Chinese were 19.7%, Indians formed 22.6% and other races made up 0.2% (see Table 1). The mean age was 58.0 years (SD 11.49) with 77.6% of them aged 50 years old and above. About 82% of the patients had their body mass index (BMI) in the overweight category ( $BMI \geq 23 \text{ Kg m}^{-2}$ ), with 42.3% of them who were actually at least in the Obese class I ( $BMI \geq 27.5 \text{ Kg m}^{-2}$ ). The mean age at diagnosis was 54.8 years old (SD 11.47) and the mean duration of diabetes was 4.7 years (SD 4.20) (see Fig.1).

TABLE 1  
Demographic profile

Profile	n (%)
Gender	
Male	8687 (42.4)
Female	11722 (57.2)
Missing	72 (0.4)
Ethnicity	
Malay	11694 (57.1)
Chinese	4026 (19.7)
Indian	4637 (22.6)
Other Malaysian	48 (0.2)
Non – Malaysian	7 (0.03)
Missing	69 (0.3)
Age group (years)	
< 30	178 (0.9)
30-49	4423 (21.6)
50-69	12424 (60.7)
$\leq 70$	3456 (16.9)

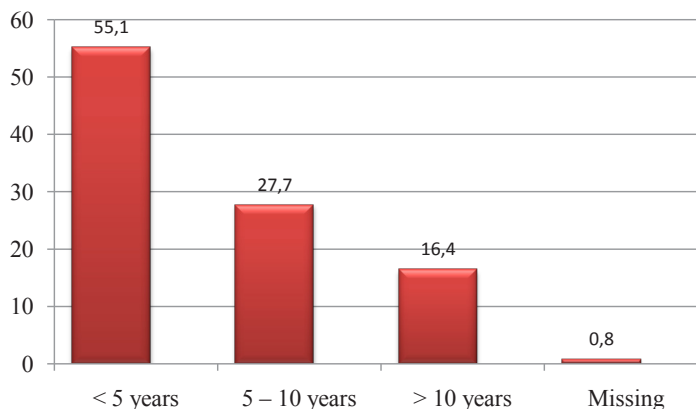


Fig. 1: The percentage of patients according to duration of diabetes

The mean casual blood glucose (CBG) and fasting blood glucose (FBG) were 11.1 mmol/L (SD 4.47) and 8.4 mmol/L (SD 3.26), respectively. The mean HbA1c was 8.0% (SD 2.10) out of about two thirds of tests carried out (Table 2). From a total of 13310 HbA1c test results available for analysis, 4012 (30.1%) of the patients attained HbA1c < 7% and 2386 (17.9%) achieved HbA1c < 6.5%.

Table 3 shows the treatment modalities of the patients. There were 326 (1.6%) patients who were prescribed diet control only. Most of the patients (42.7%) were on two and more oral anti-diabetic agents (OAD) as compared to monotherapy of OAD (34.9%). The most common OAD was either Metformin (75.9%) or a sulfonylurea (60.8%). Insulin was prescribed in a total of 2254 (11.0%) patients with about two thirds of them were prescribed in combination with OAD agents (see Table 3). Amongst the patients on insulin therapy, intermediate acting insulin was the most commonly used insulin (53%), followed by pre-mixed insulin (38.9%) and the least used was long-acting insulin (0.01%).

TABLE 2  
Glycaemic monitoring and profiles from July-December 2008

Measurement	n, (% of the total patients)	Mean (SD)
Casual blood glucose (mmol/L)	11200 (54.7)	11.1 (4.47)
Fasting blood glucose (mmol/L)	14214 (69.4)	8.4 (3.26)
2 hrs Post-prandial (mmol/L)	5825 (28.4)	13.3 (4.58)
HbA1c (%)	13764 (67.2)	8.0 (2.10)

TABLE 3  
Treatment Modalities

Treatment Modalities	n (%)
Diet only	326 (1.6)
Oral anti-diabetic agent only	
- Monotherapy (OAD)	7142 (34.9)
- $\geq 2$ OAD	8753 (42.7)
OAD & Insulin	1415 (6.9)
Insulin only	839 (4.1)

## DISCUSSION

There was a huge majority of T2D (99.2%) in the registry as it was expected from the mainly primary care set-ups of the site data providers. Hence, Type 1 diabetes mellitus patients were rarely seen at these health clinics, as few as an average of less than 2 patients per centre. Negeri Sembilan contributed the most number of patients because this project was initiated in this state from the beginning. The gender composition was typical of attendance to any of the Malaysian health care centres and services, whereby female attendance (57.2%) being more common than the male. However, the difference was not as large as usually seen, most probably owing to the fact that a large majority of patients were retired individuals (77.6% being older than 50 years old). The ethnicity composition did not reflect the national representation as evidenced by the Indians (22.6%) being the second most common users of these health facilities instead of the Chinese (19.7%). This phenomenon is not unexpected since the Indians are the ethnic group mostly affected by diabetes and the Chinese could be getting their health care needs from the private health care sectors (National Health Morbidity Survey, 1996; Institute of Public Health, 2008). This registry confirmed the belief that most of the T2D patients seen at the primary care level were at the early stage of the disease as there were more than half who were diagnosed less than 5 years ago.

FBG was the most commonly carried out test for the patients and this was closely followed by HbA1c; about two thirds (67.2%) of the patients managed to have HbA1c tested in the past one year. This was comparable to another study in 19 public hospitals across Peninsular Malaysia which reported annual testing rates of 67.9% for HbA1c (Mafauzy, 2006). The mean HbA1c of 8.0% in this survey was better when compared to data of 8.6% from tertiary centres and hospitals (Ismail *et al.*, 2000). However, the figure is higher than in another study conducted in a government primary health centre in East Malaysia, where the average HbA1c was 7.4% (Wong & Rahimah 2004). This survey found that 30.1% of the patients attained HbA1c < 7% and 17.9% achieved HbA1c < 6.5%. The control profile was rather similar to both the local and United States academic primary care centres (Eid *et al.*, 2004; Chew *et al.*, 2011; McFarlane *et al.*, 2002). Studies in public hospitals (Mafauzy, 2006) and another study in an urban primary health care centre (Wong & Rahimah, 2004) have shown better results. The reason for the difference could be due to the level of care. Patients from hospital and urban health clinics are mainly managed by specialist or senior medical officers whereas our survey included rural districts where the patients may be managed by medical assistants or

junior medical officers. Lack of awareness and adherence to clinical guidelines, heavy patient load and restricted access to “List A” drugs like premixed insulin and safer sulphonylurea, glicazide may be the other factors for poorer results in the public primary healthcare clinics in our survey (Tan *et al.*, 2008).

We observed that a few patients were on diet control alone as their treatment. This was not surprising among the present study cohorts of patients in the early stage of diabetes mellitus who might be asymptomatic and had HbA1c < 6.5% or FBG < 6.0 mmol/L in accordance to the recommendation of the national clinical practice guidelines (Malaysian Clinical Practice Guidelines for the Management of Type 2 Diabetic Mellitus, 2009). This registry reported a positive finding that more metformin than sulphonylureas was prescribed now compared to earlier studies in the country (Sarojini *et al.*, 2008) and Thailand (Kosachunhanun *et al.* 2006) that showed the reverse scenario. The first line of anti-diabetic with metformin was appropriate in this youngish cohort and contra-indication of metformin is rather rare in primary healthcare clinical practice. This similar observation was also noted in the United Kingdom general practice since 2002, when metformin use surpassed sulphonylureas (Filion *et al.*, 2009). However, the insulin use, both alone and in combination with other OAD agents, was still very low (11%) and this may explain rather poor diabetic control rate amongst the T2D patients in the community. The National Health Morbidity Survey in 2006 showed only 7.2% insulin usage, both alone and in combination with oral anti-diabetics. Under-utilization of insulin is also found in other studies in primary care clinic and hospital (Wong & Rahimah, 2004; Tan *et al.*, 2008). This could be due to the resistance to use insulin by the healthcare provider and the low acceptance of insulin therapy by patients due to misconception of insulin risk and interference of routine life-style (Nathan, 2002; Cefalu, 2002; Karter *et al.*, 2010).

The limitations of this registry are the retrospective data retrieval from patients’ records by mainly non-treating parties leading to incompleteness and inaccuracy. As the registry was not compulsory, many health centres did not participate, leading to biased patient population from only the participating centres. Thus, the data presented here could not be generalized to the whole primary care in Malaysia as a major proportion of the patients were from Negeri Sembilan.

## CONCLUSION

ADCM-DRM is gaining momentum since its inception as evidenced by the ever increasing number of site participation and patients registered into the registry. The control profile was rather fair and showed no improvement as compared to earlier glycaemic control profile in the country many years ago. There was under-utilization of insulin which could have caused poor glycaemic control in the majority and this insulin acceptance and adherence can be improved with better patient education and self-management training. A review of the diabetic care policy and strategies in the primary health care clinics is needed to implement a more effective treatment of diabetes.

## ACKNOWLEDGEMENTS

We would like to acknowledge the Director General of Health for their support in our effort in the registry and permission to publish this article using the data from public health clinics. We would like to express our sincere gratefulness to Ms Lena Yeap, Noor Akma Hassim and Tee Chin Kim from CRC, Kuala Lumpur.

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