The Status of Diabetes Control in Malaysia: Results of DiabCare 2008

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SUMMARY

DiabCare Malaysia 2008 evaluated the current status of diabetes care in Malaysia as a continuation of similar cross-sectional studies conducted previously in 1997, 1998, 2001 and 2003. The current study recruited 1670 patients from general hospitals, diabetes clinics and referral clinics to study current scenario of diabetes management. We report the results of type 2 diabetic population who constituted 92.8% (n=1549). Results showed deteriorating glycaemic control with mean HbA1c of 8.66±2.09% with only 22% of the patients achieving ADA target of <7%. 80.3% of patients were hypertensive and 75% were on anti-hypertensive medication. 46% of patients had LDL levels >2.6 mmol/L; 19.8% had triglycerides >2.2 mmol/L; 27.4% had HDL<1 mmol/L despite 85% of the patients being on lipid lowering agents. Microvascular, macrovascular and severe late complications were reported in 75%, 28.9% and 25.4% patients respectively. The rates of diabetic complications were cataract 27.2%, microalbuminuria 7%, neuropathy symptoms 45.9%, leg amputation 3.8% and history of angina pectoris was 18.4%. Quality of life evaluation showed that about one third of patients have poor quality of life. Also, there was poor adherence to diet, exercise and self testing of blood glucose. In conclusion, majority of the patients were still not satisfactorily controlled. There is an urgent need for effective remedial measures to increase adherence to practice guidelines and to educate both patients and healthcare personnel on importance of achieving clinical targets for metabolic control.

KEY WORDS:
DiabCare, Diabetes care, Diabetes complications, Glycaemic control, Hypertension, Dyslipidaemia

INTRODUCTION

Diabetes mellitus (DM), a complex disorder mostly associated with obesity, is turning into an epidemic worldwide, imposing burden on individuals and society with staggering economic costs and low productivity[1]. The Asia pacific region with an estimated diabetes-affected population of 135.4 million in 2010 is at the forefront of the current epidemic[2]. The rise in prevalence is more in developing countries with an estimated projection, of 170% compared to 42% in developed countries to the year 2025[3,4]. Malaysia, a rapidly developing economy, comprising a multi ethnic population possesses all the favorable environment to support diabetes progression and its complications viz. urbanization, westernization and sedentary life style[5]. People with diabetes in Malaysia have almost doubled in a span of 2 decades from 6.3% in 1986 to 11.6% in 2010, with a WHO prediction of a total affected population of 2.48 million by 2030[6].

With this increase in prevalence of diabetes, it has become imperative to monitor diabetes management, control strategies and complication profile for improvement in quality of care. In pursuit of the above, DiabCare Asia, a multinational project was initiated in 1997 with Malaysia as one of the participating countries. The DiabCare Malaysia studies of 1997 and 1998 depicted a lack of adequate glucose control and complications in majority of the patients managed at public hospitals. The results motivated the involvement of the Ministry of Health to initiate diabetes resource care centres, training and awareness programmes for diabetes nurse educators. This was also supported by expanded availability of HbA1c tests in hospitals and clinics. Nevertheless, DiabCare 2001 study from primary health care centers failed to show good control with a high prevalence of complications. The next DiabCare study in 2003 in specialist centres reported a slight reduction in complication rates compared to 1998, however, control of disease was still unsatisfactory[6]. After successful completion of 4 previous DiabCare projects undertaken in 1997, 1998, 2001 and 2003, "DiabCare" 2008 was designed as a cross-sectional, observational study, to assess the current scenario of diabetes management and included more or less the same centres as that of the previous studies for further evaluation in improving diabetes care.

MATERIALS AND METHODS

The data was collected from 6th April 2009 to 30th December 2009 on patients with diabetes recruited from general hospitals, diabetes clinics and referral clinics throughout the country. The primary objective was to evaluate diabetes management, control and complication profile in patients with diabetes. Secondary objectives included studying psychosocial aspects of diabetic patients and to evaluate perceptions and practices of physicians about diabetes management. Patients with diabetes registered in the particular center for more than a year with at least one visit in the 3-6 months preceding the study were included. Eligible patients were explained the study purpose and invited to attend another clinic visit. Informed consent was obtained

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from these patients. Data was collected during the study visit by review of medical records, clinical examination, laboratory assessments and personal interview. The data from medical records consisted of demography, medical history, risk factors, self-monitoring of blood glucose (SMBG) data, diabetes education, complications, eye and foot examinations, diabetes management and HbA1c.

Data collected during the study visit was systematically captured in standardized case report forms (CRFs) designed for this study. Novo Nordisk was responsible for collecting completed CRFs from participating centres and for data management. Subject perception of treatment practices was evaluated with the help of subject questionnaire for quality of life which contained 3 parts: WHO-5 well being Index[7], psychosocial and treatment adherence questionnaire (adapted from the DAWN survey)[8]. The questionnaires were administered to recruited subjects during the interview. The results of patients with only type 2 diabetes are presented in this report.

HbA_{1C} Measurement
The method used for estimation was BioRad HPLC D10. The blood samples from all the study subjects during the study visit were collected in Sodium-heparinised capillaries, hemolysed in aqueous solution and stored between -20^0 C to -80^0 C in the respective centres until collected by the centralized laboratory. All blood samples were transported to the central laboratory within 24 hours for testing. The blood samples after HbA1C analysis were promptly disposed[9].

Statistical Analysis Plan
The data set for analysis was confined to the following range of values for various parameters viz. age (18-85 years), BMI (18-40 Kg/m^2), HbA1c (4-16%), FPG 54-306 mg/dl (3-17 mmol/), PPG 54-500 mg/dl (3-27.77mmol/l) and the duration of diabetes up to 25 years.

Statistical methods were similar to those of the earlier published DiabCare studies [6]. Descriptive statistics were used to summarize continuous variables; primary endpoints presented as mean ± standard deviation (SD), range or percentage and secondary endpoints as number and percentage. Logistic regression was used to analyse the relationship between complications (cataract, serum creatinine >2mg/dl, symptoms of neuropathy and macrovascular complications – all expressed as a binary outcome, present or absent) and risk factors [predicted by age, sex (male or female), age at onset, duration of diabetes, hypertension (present or absent), insulin therapy (yes or no), HbA1c, FPG and SMBG (testing done or not done)]. Adjusted odds ratios for all complications were computed for two of the predictor variables viz., age at onset and duration of diabetes. All tests were two-sided and a p value of less than 0.05 was considered to be significant.

RESULTS

A total of 1670 patients participated in the study, with majority (n=1549, 92.8%) having type 2 diabetes. The response rate was more than 90% in majority of the study variables. However, the response rate was lower for waist circumference (59%), BMI (46%), eye complications (cataract – 64%, photocoagulation – 64%, advanced eye disease – 63% and legal blindness – 68%) and neuropathy evaluation (symptoms – 63%, monofilament testing – 62% and ankle jerk reflex testing – 36%).

Patient Demography Characteristics
Demographic and metabolic characteristics of type 2 population are elaborated in Table I.

Metabolic Control
Glycemic Parameters
The frequency of testing for FPG and HbA1c was 2.71 ± 1.6 and 2.47 ± 1.0 times respectively over the preceding one year. Data on PPG was available for a small proportion of patients (200/1549, 12.9%). The mean values for glucose measures were HbA1c 8.66 ± 2.09% (n=1496), FPG 7.98 ± 2.92 mmol/L (n= 1214) and PPG 12.96 ± 4.82 mmol/L. The proportions of target achievers are given in Table II. With increase in duration of diabetes, there was a significant increase in mean HbA1c ($p<0.0001$) and FPG ($p=0.05$) i.e 7.32 ± 1.5% and 6.86 ± 2.3 mmol/L for < 1year, 8.34 ± 2.1% and 7.94 ± 2.8 mmol/L for 1-5 years, 8.47 ±1.9% and 7.97 ± 2.9 mmol/L for >5 – 10 years, 8.83 ± 1.9% and 8.12 ± 3.0 mmol/L for duration of > 10 years respectively.

Lipid Parameters and BP control
The proportion of patients with dyslipidemia was 96.1% (1489/1549). However, 95.6% (1481/1549) had undergone lipid measurements in last one year. The mean LDL, HDL and triglycerides levels were 2.69 ± 0.98, 1.13 ±0.69 and 1.64 ± 1.22 mmol/l respectively. The proportion of patients exceeding the AHA-recommended targets[10] were 46% (712/1549) for LDL>2.6 mmol/l, 27.4% (424/1549) for HDL<1 mmol/l and 19.8% (307/1549) for triglycerides >2.2 mmol/l. Overall, 85% (1316/1549) were receiving lipid lowering drugs - Statins 95.5% (1257/1316) and fibrates 9.2% (121/1316). 80.3% (1244/1549) were hypertensive having a mean SBP/DBP of 137.10±19.6/ 78.9±11.27 mm Hg. 39.1% (605/1549) reported a blood pressure of ≤130/80 mmHg. 75% (1161/1549) were on anti-hypertensive medication viz. ACE inhibitors (757/1161, 65.2%), calcium channel blockers (697/1161, 60%), beta blockers (537/1161, 46.3%), Angiotensin II receptor blockers (425/1161, 36.6%) and diuretics (424/1161, 36.5%).

Complication Status
The proportions of patients evaluated for various diabetic complications were: diabetic eye complications 1051/1549 (67.9%), diabetic nephropathy 1508/1549 (97.3%), diabetic neuropathy 986/1549 (63.7%), foot complications 741/1549 (47.8%) and cardiovascular disease 1541/1549 (99.5%). The prevalence of microvascular (retinopathy, nephropathy and neuropathy) and macrovascular (Angina pectoris, MI, CABG/Angioplasty/Stents and stroke) complications was 75% (1161/1549) and 28.9% (446/1549) respectively. 25.4% (390/1549) had severe late complications (legal blindness, MI, CABG/Angioplasty/ Stents, Cerebral stroke, ESRD and Leg amputation). Most of the complications increased with duration of diabetes (Table III).

Serum creatinine (98%, 1474/1508) was the most used modality for assessing renal function with 10% (152/1508) reporting values above 2 mg/dl. Microalbuminuria testing

was done in 28.7% (433/1508) with 7% (107/1508) testing positive (30-300 mg/L) and 4.5% (68/1508) having macroalbuminuria (>300mg/L). 14 patients (0.9%) were in end-stage renal failure requiring dialysis or transplant.

Out of 986 patients who were evaluated for diabetic neuropathy, 45.9% (453/986) had symptoms, 42.2% (416/986) underwent monofilament testing with 40.6% (169/416) testing positive (no sensation perceived). Ankle jerk was absent in 30.9% (305/986) of patients.

Cataract (286/1051, 27.2%) and non-proliferative retinopathy (240/1051, 22.8%) were the most commonly reported eye complications. Severe late eye complications reported were photocoagulation (161/1051, 15.3%), proliferative diabetic retinopathy (144/1051, 13.7%), advanced eye disease (56/1051, 5.3%) and legal blindness (18/1051, 1.7%).

741 patients were evaluated for diabetic foot complications. Absence of foot pulses 5% (37/741), healed ulcer 3.9% (29/741), leg amputation 3.8% (28/741), vascular surgery/ angioplasty 2% (15/741) and active ulcer / gangrene 1.5% (11/741) were reported.

Amongst the cardiovascular complications, history of angina pectoris, myocardial infarction, CABG/Angioplasty and stroke were reported in 18.4% (283/1541), 12.1% (186/1541), 13% (200/1541) and 6.9% (106/1541) patients respectively. Use of anti-platelet drugs including aspirin was reported in 58.4% (905/1549).

Infections were reported in 4.6% (71/1549) of patients. The various infections reported were: foot 27% (19/71), skin 24% (17/71), respiratory 20% (14/71), urinary tract 15.5% (11/71) and eye (1 patient) infections. History of erectile dysfunction was reported by about the half the male population (349/708, 49%).

Diabetes Management

The proportions of patients on OADs and insulin were 79.3% (1283/1549) and 53.6% (831/1549) respectively. Mean duration of OAD and insulin treatment were 11.0±8.27 and 4.21±4.6 years respectively. The proportions of patients using different OADs were biguanides 89.2% (1144/1283), sulphonylureas 54.8% (703/1283), alpha glucosidase inhibitors 11.4% (146/1283), thiazolidinediones 6% (77/1283), DPP-IV inhibitors 1.8% (23/1283), meglinitides 0.8% (10/1283) and traditional therapies 0.5% (6/1283). Majority of insulin-treated patients (82.4%, 685/831) were taking human insulin and 19.4% (161/831) were on analogue insulin. Types of insulins used were premix 50% (416/831), basal 26.4% (219/831), basal-bolus 19.5% (162/831) and bolus alone 9.6% (80/831). The mean dose of insulin was 50.9 ± 32.3 U/day and the mean number of injections was 2.3 ± 1.1 per day. The proportions of patients receiving once-, twice- and more than twice-daily injections were 23.2% (193/831), 48.0% (399/831) and 26.4% (219/831) respectively. Insulin was administered by a pen device in 94% (781/831), by a syringe in 2.3% (19/831) and by both pen and syringe in 2 (0.24%) [Missing data 29 (3.5%)].

The mean numbers of sessions in various aspects of diabetes education over the last year were as follows: Diet 1.6 ± 1.0, exercise 1.6 ± 1.0, SMBG 1.6 ± 1.2, foot care 1.5 ± 1.3 and general diabetes education 1.7 ± 1.2. 58.7% (910/1549) performed SMBG regularly & the mean number of tests conducted per month was 11.5 ± 14.1.

Quality of Life and treatment adherence

The responses to WHO-5 well-being index, psychosocial and treatment adherence questionnaires are shown in Table IV.

DISCUSSION

Results of DiabCare Malaysia 1997 prompted the Government Ministry of Health in Malaysia to set up Diabetes Resource Centres across the country and the key initiatives that followed were training of diabetic nurse educators and availability of HbA1c test [6]. DiabCare Malaysia 2008, a cross-sectional survey provided an overview of the diabetes care rendered in the last one year. It provides a better understanding of the trends in quality of care and the implementation of learning from the previous study.

The mean age of patients with type 2 diabetes in the current study (57.5 ± 10.9) is slightly more than that of DiabCare 2003 (55.8 ± 11.4). The duration of diabetes and age at onset also have increased from 10.8 ± 7.9 to 11.46 ± 8 years and 44.9 ± 12.0 to 46.4 ± 11.03 years respectively. Female preponderance (52.9% vs. 53.5%) was seen in both DiabCare 2008 and 2003[6].

In this study mean BMI (27.8 kg/m^2) of patients was higher than that in 2003 (26.7kg/m^2). 72% were obese as compared to 66.5% of patients in the last DiabCare study. Again, males had a lower mean BMI (27.5±4.2 kg/m^2) than that of females (28.0±4.8 kg/m^2). Undesirable waist circumference was reported in a higher number of females (≥80 cm in 89.4%) than males (≥90 cm in 73.7%). These proportions showed an increase from DiabCare 2003 when 82.1% females and 69% males reported undesirable cut-off values. In the present study, the data on body weight and circumference measurements was obtained only in around half of the patient population (N=844). However, the results are consistent with earlier DiabCare studies. A recent study by Zaher M *et al* showed a lower BMI of 23.5 kg/m^2 in men and 24.9 kg/m^2 in women [11]. A waist circumference of 83 cm in men and women was considered to be suitable in defining criteria for overweight or obesity among adults in Malaysia[11]. Increased CVD risk related to obesity at lower BMI cut-off levels has been found in Asians[12]. Furthermore, waist circumference appeared as a better predictor of diabetes and obesity-related cardiovascular risk factors than BMI[13]. Thus, obesity may be a cause of increasing insulin resistance and prevalence of diabetes in the Malaysian population.

Glycemic control has shown deterioration with mean HbA1c in DiabCare 2008 (8.66±2.09%) being greater than that of 2003 (7.8±2.2%). In addition, the percentage of patients achieving HbA1c glycemic targets has been the lowest since the DiabCare 1998 study (Supplementary appendix Table a). In DiabCare 2008, 96.5% of patients had HbA1c measured

Table I: Demographic and metabolic characteristics

Demographic And Metabolic Characteristics	Data
Age (years)*	57.5 ± 10.9
Gender, male/female	708/ 794 (45.7/51.3%)
BMI (kg/m^2)*	27.8 ± 4.5
BMI groups:	
≥23 / ≥25 kg/m^2	
85.4 / 72%	
Duration of diabetes (years)*	11.5 ± 8.0
Waist circumference: (%)	
Male (≥90 cm) / Female (≥80 cm)	
73.7 / 89.4 %	
Duration of diabetes groups: (%)	
≤1 / 1-5 / >5-10 / >10 years	2.8 / 24.7 / 28.2 / 43.5 %
Age at onset (years)*	46.4 ± 11.0
Educational status	
LCTRW#	123 (7.9%)
5 years	359 (23.2%)
10 years	741 (47.8%)
Graduate	263 (17.0%)
Postgraduate	40 (2.6%)
Risk factors	
Family history	1057 (68.3%)
Smoking	140 (9.0%)
Alcohol	77 (5.0%)
Health expenses	
Government/ Community	1344 (86.8%)
Self	193 (12.5%)
Insurance	2 (0.1%)
Ethnic groups	
Malay	855 (55.2%)
Chinese	334 (21.6%)
Indian	308 (19.9%)
Others	52 (3.4%)

* Data expressed as mean ± SD. BMI, body mass index; OAD, oral antidiabetic drug; SU, Sulphonylurea; BG, Biguanide; AGD, Alpha glucosidase inhibitors; TZD, Thiazolidinediones; #Limited Capacity To Read and Write Main cohort, type 2 diabetes mellitus, n=1549

Table II: Glycaemic target achievers

Variables	Ada Guidelines		Eu Guidelines		Idf/ Aace Guidelines	
	Target	N (%)	Target	N (%)	Target	N (%)
HbA1c (%)	< 7	341 (22.0)	≤ 6.5	200 (12.9)	< 6.5	176 (11.4)
	≥ 7	1154 (74.5)	> 6.5	1295 (83.6)	≥ 6.5	1319 (85.2)
FPG (mmol/dL)	≤ 7.22	599 (38.7)	≤ 6	369 (23.8)	< 6.1	370 (23.9)
			> 6 - < 7	195 (12.6)		
	> 7.22	614 (39.6)	≥ 7	649 (41.9)	≥ 6.1	843 (54.4)

Main cohort, n=1549. ADA, American Diabetes Association; EU, European Diabetes Policy Group; IDF, International Diabetes Federation; AACE, American Association of Clinical Endocrinologists

Table III: Prevalence of diabetic complications stratified by duration of diabetes

	Duration Of Diabetes Categories			
Diabetic Complications	≤1 year	>1 – 5 years	>5-10 years	>10 years
Cataract (N=1051)	6 (0.6)	38 (3.6)	65 (6.2)	171 (16.3)
Non-proliferative diabetic retinopathy (N=1051)	6 (0.6)	38 (3.6)	53 (5.0)	139 (13.2)
Photocoagulation (N=1051)	2 (0.2)	14 (1.3)	23 (2.2)	119 (11.3)
Microalbuminuria* (N=433)	3 (0.7)	28 (6.5)	28 (6.5)	44 (10.2)
Leg amputation (N=741)	0 (0)	4 (0.5)	3 (0.4)	21 (2.8)
Absent foot pulses (N=741)	0 (0)	5 (0.7)	12 (1.6)	20 (2.7)
Neuropathy symptoms (N=986)	10 (1.0)	82 (8.3)	120 (12.2)	238 (24.1)
Myocardial infarction (N=1541)	2 (0.1)	43 (2.8)	54 (3.5)	84 (5.5)
Cerebral stroke (N=1541)	1 (0.06)	23 (1.5)	28 (1.8)	53 (3.4)
Angioplasty (N=1541)	1 (0.06)	36 (2.3)	50 (3.2)	109 (7.1)

* 30 – 300 mg/L; N=number of patients evaluated for each complication; numbers in parentheses indicate % out of N

Table IV: Psychological well-being, quality of life and treatment adherence – the DiabCare Malaysia 2008 study

	% Positive*	% Negative$^{\Psi}$
Psychological well-being[a]		
P1. I have felt cheerful and in good spirits	59.1	38.3
P2. I have felt calm and relaxed	66.1	31.6
P3. I have felt active and vigorous	56.0	41.3
P4. I woke up fresh and rested	59.5	38.2
P5. My daily life has been filled with things that interest me	68.8	28.2
Quality of life[b]		
Q1. I feel my diabetes is well regulated	69.6	25.6
Q2. I am constantly afraid of my disease getting worse	34.0	63.1
Q3. I am tired of complying with my medications	59.7	37.7
Q4. I feel that my diabetes is preventing me from doing what I want to do	57.8	39.6
Q5. I am worried about the risk of hypoglycaemic events	35.8	54.3
Q6. Coping with diabetes is more difficult at present than it used to be	62.5	29.8
Q7. I feel burned out from having to cope with diabetes	62.0	34.6
Subjects not using insulin[c]		
S1. I am very worried about having to start on insulin	28.3	61.3
S2. Starting on insulin would mean I have not followed my treatment recommendation properly	27.3	61.3
Treatment adherence[d]		
Diet	84.6	12.0
Exercise	57.2	38.6
Taking medications as prescribed	95.9	1.7
Testing yourself	51.8	41.9
Keeping appointments with health care professionals	96.8	0.5

* Answered all/ most of the time OR fully/ mainly disagree (except Q1) OR completely/ partially; Ψanswered some of the time/ not at all OR fully/ mainly agree (except Q1) OR rarely/ never
[a,b,c,d]Excluded answer to category: 'don't know/refused'

Table V: Percentage of patients achieving glycemic targets in DiabCare 2008, 2003 and 1998

Guideline	Targets	2008	2003	1998
HbA1c (%)				
ADA	< 7%	22.0	41	27
EU	< 6.5%	11.4	31.2	14
AP	≤ 7.5%	36.2	52	40
FPG (mmol/dL)				
ADA	≤ 7.22	38.7	34.3	-
EU	≤ 6.0	23.8	18.1	18
	> 6 - ≤ 7	12.6	11.9	-
AP	≤ 6.1	25.0	18.1	-

ADA, American Diabetes Association; EU, European Diabetes Policy Group; AP, Asia-Pacific Type 2 Diabetes Policy Group

Table VI: Odds for diabetes-related complications in type 2 diabetes mellitus

Independent Variable	Cataract	Serum Creatinine >2mg/Dl	Neuropathy Symptoms	Macrovascular Complications
Age	1.07 (1.05-1.08)*	1.03 (1.01-1.05)*	1.01 (1.00-1.02)	1.05 (1.04-1.07)*
Sex	0.94 (0.71-1.24)	0.50 (0.35-0.71)*	1.03 (0.80-1.32)	0.37 (0.29-0.47)*
Age at onset	1.02 (1.00-1.03)*	0.99 (0.98-1.01)	0.98 (0.97-1.00)*	1.02 (1.01-1.03)*
Duration	1.06 (1.03-1.07)*	1.05 (1.03-1.07)*	1.05 (1.03-1.06)*	1.03 (1.02-1.05)*
Hypertension	4.26 (2.1-8.60)*	6.10 (1.91-19.42)*	1.66 (1.08-2.57)*	5.11 (2.80-9.35)*
On insulin	1.79 (1.33-2.40)*	4.76 (3.01-7.53)*	2.08 (1.60-2.70)*	1.23 (0.97-1.54)
HbA1c	1.00 (0.93-1.07)	1.01 (0.93-1.10)	1.17 (1.10-1.24)*	0.98 (0.93-1.04)
FPG	1.03 (0.98-1.08)	1.00 (0.94-1.07)	1.09 (1.03-1.14)*	1.03 (0.99-1.08)
SMBG	1.00 (0.75-1.33	1.04 (0.74-1.46)	0.86 (0.67-1.11)	0.90 (0.72-1.13)

Data presented as odds (95% confidence interval); *p<0.05; FPG, Fasting Plasma Glucose; SMBG, Self monitoring of blood glucose
Odds for binomial data: Odds for "sex" expressed as male vs female; odds for "hypertension" expressed as the reciprocal of subjects with SBP ≥140 mmHg or DBP ≥90 mmHg or use hypertensive medication vs. non-hypertensive subjects; odds for "SMBG" expressed as subjects doing SMBG vs. subjects not doing SMBG; odds for "On insulin" expressed as subjects with insulin therapy vs. subjects without insulin therapy. Age, Duration of diabetes, HbA1c, FPG and onset age were continuous variables
Macrovascular complications: Patients with any or all of the below mentioned complications - Angina pectoris, MI, CABG/Angioplasty/Stents, Stroke

Table VII: Proportion of patients on lifestyle modification and therapy

Variables	2008	2003
Diabetic Diet: Regularly/ Seldom	34.0/ 12.0*	54.8/ 39.9
Exercise: Regularly/ Seldom	26.9/ 38.6*	38.9/ 36.9
Smokers	9.0	8.6
Alcohol	5.0	5.6
OAD	79.3	86.7
Insulin	53.6	28
Insulin Frequency:		
Once-daily/ Twice-daily/ 3 or more injections/day	23.2/ 48.0/ 26.4	15/ 60.3/ 13
Regular self monitoring	58.7	26.8

OAD, oral antidiabetic drug; *Regularly – responses taken as "Completely" and Seldom – responses taken as "rarely" or "never"

over the last one year as compared to 67.9% of patients in 2003. This reflects an increasing awareness among both patients and physicians regarding HbA1c testing and the wide implementation of the steps undertaken by Ministry of Health since 1998 towards availability of HbA1c tests & nurse educators in various health care facilities. However mean FPG in this study (7.98±2.92 mmol/l) has improved over the 5 years since the last study (9.5±4.0 mmol/l in 2003). This is reflected in the increase in proportion of patients achieving the FPG targets as per various guidelines (Table V). With two-thirds of the patients not adhering to advice on diet and exercise and majority of the patients with formal education of less than 10 years, lifestyle factors and uncontrolled postprandial glucose (PPG) may underlie the poor status of glucose control as shown by HbA1c. PPG contributes approximately 70% to the total glycemic load in patients who are fairly well controlled (HbA1c <7.3%)[14]. Numerous epidemiological and observational studies have demonstrated an association between postprandial hyperglycaemia and cardiovascular mortality in patients with diabetes. Emerging evidence also suggests that treating PPG may prevent the development of CVD[15]. The prevailing situation demands more awareness, initiatives and efforts about glucose profiling and lifestyle modification for effective management of diabetes and reducing cardiovascular burden.

When compared with the 2003 study, there was an increase in the number of patients with dyslipidemia (68% vs 96.1%) which is consistent with the higher prescription (52.8% vs 85%) of lipid lowering drugs. The proportion of patients who achieved the AHA-recommended targets were 54% for LDL<2.6 mmol/l, 72.6% for HDL>1 mmol/l and 56.2 % for triglycerides <1.7 mmol/l. However, in 2003 only 32% of the patients had total cholesterol < 4.8 mmol/l, 39.6% patients had HDL cholesterol > 1.1 mmol/l & 51.1% had TG < 1.7 mmol/l[6]. These show an overall improvement in management of dyslipidaemia, however, a large proportion of the patients have not achieved the recommended lipid targets. Although medications can improve lipid levels, dietary compliance is important and issues of lifestyle modifications need to be emphasized.

The number of patients taking treatment for hypertension as compared to DiabCare 2003 study was almost the same (75% in 2008 vs 75.9% in 2003). However, the proportion of patients at target ≤130/80mmHg has more than doubled from 11.3% in DiabCare 2003 study to 39.1% in the present study indicating improvements in state of care.

Increased prevalence of complications in evaluated patients in the present study calls for more focus on optimal metabolic control. The prevalence of cataract (28.9% vs. 16.2%), advanced eye diseases (5.8% vs. 5.4%) and legal blindness (1.7% vs. 0.8%) recorded in the present study were higher than in the DiabCare 2003 study. While only 19% had neuropathy in 2003, 46.4% reported symptoms of neuropathy in this study[6]. With regard to microalbuminuria testing, only half the population was tested in the past one year.

Cardiovascular complications and stroke appear to be higher in the present study as compared with the 2003 study (MI/angioplasty - 10.2%, stroke - 5.3%). There are some differences in rates of foot complications from those reported in DiabCare 2003 study notably absent foot pulses (5% in present study vs 1.5% in 2003), healed ulcer (3.9% vs 5.4%) and leg amputation (3.8% vs 2.3%)[6]. The low evaluation rates for various diabetic complications viz. diabetic foot examination (42.8%), neuropathy (63.7%) and eye complications (67.9%), suggest scope for improving screening protocols in routine practice.

Age at onset and duration of diabetes emerged as significant predictor variables for all selected complications except for symptoms of neuropathy for which only duration of diabetes was significant. However, other variables were also able to predict selected complications as shown by the unadjusted odds ratio (Table VI). The odds of complications were higher in patients with hypertension and those treated with insulin. However, Insulin therapy was not a significant predictor of macrovascular complications. Blood glucose measures of HbA1c and FPG could only predict symptoms of neuropathy. Earlier DiabCare studies of 1998[16] and 2001[17] have reported onset of age and duration of diabetes as independent predictors of various diabetic complications. Hypertension was also a significant predictor of stroke in these studies. Thus earlier treatment of diabetes and good control of hypertension emerge as important factors in preventing or controlling complications in successive DiabCare studies.

Use of biguanides has increased while use of secretagogues (sulphonylureas and meglinitides) has decreased relative to 2003 study. This is according to the clinical practice guidelines' recommendation of biguanide as the preferred 1st-line oral antidiabetic agent . The proportion of patients using OAD monotherapy has increased since 2003 (37.2% in the present study vs 22.5% in 2003), that of 2 OADs have decreased (32.3% vs 36.5%) and ≥3 OADs have also increased

(11% vs 9%). However, insulin prescriptions have almost doubled as compared to 2003 - insulin alone (15.4% in present study vs. 12.7% in 2003), insulin + OADs (38.3% vs 14.4%). The data on type of insulin regimen used is not available from earlier studies. The proportion of once-daily injection users and three or more injection users have increased while the twice-daily injection users have decreased since 2003. Also, in the present study, the proportions of once-, twice- and more than twice daily injection users correspond approximately with those of basal, premix and basal-bolus regimens (Table VII). Thus, we speculate that more patients are being initiated and intensified on insulin therapy.

Responses to the WHO-5 well-being index suggested that most of the patients (55.7% - 73.6%) perceived a healthy state of well-being. However, the more disease-specific DAWN QoL questionnaire showed that about the half the patient population experienced an increased burden of disease with negative responses to almost all the questions (Table IV). The adherence to treatment questionnaire indicated that about one-third of patients were partially or not adherent to therapy related advice. The above, along with the reported results on diabetic education sessions indicate that more awareness needs to be created on lifestyle modification and self-testing. The DAWN QoL responses also call for increasing awareness and benefits of insulin therapy and of measures to avoid hypoglycaemia.

CONCLUSION

The results of the current study reflect the good initiatives by the Ministry of Health and effective implementation on a few fronts in routine diabetes care. These include increased availability of HbA1c testing, improved fasting plasma glucose, improved diagnosis and testing of co-morbid conditions (dyslipidaemia and hypertension) and a doubling of insulin use in the population. However, the increase in mean HbA1c and the decreasing proportion of patients achieving targets when compared to earlier studies call for reassessment of current management practice with recommendations to be implemented to address this suboptimal status. . The prevalence of diabetic complications tended towards an increase since the earlier study and the screening for some diabetic complications was not optimal (microalbuminuria and foot examination). Age at onset, duration of diabetes and presence of hypertension has consistently emerged as independent and significant predictors of complications in the present as well as earlier studies. These should continue to receive focus in routine diabetes care. The responses to patient reported outcome tools (WHO-5, DAWN QoL and Treatment adherence) call for more efforts to improve lifestyle modification, self-testing and awareness and benefits of insulin therapy. As with earlier DiabCare studies, the present study also uncovers gaps in routine diabetes care and will help plan future interventions and monitor outcomes.

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REFERENCES

1. Economic consequences of diabetes mellitus in the U.S. in 1997. American Diabetes Association. Diabetes Care 1998; 21: 296-309.
2. IDF Diabetes Atlas 4th edition, © International Diabetes Federation, 2009.
3. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995-2025: prevalence, numerical estimates, and projections. Diabetes Care 1998; 21: 1414-31.
4. The World Health Report 1997, WHO Switzerland. Link: http://www.who.int/whr/1997/en/whr97_en.pdf (accessed 01 Sept 2010).
5. Ismail IS *et al*. Socioedemographic determinants of glycaemic control in young diabetic patients in peninsular Malaysia. Diab Res Clin Pract 2000; 47: 57-69.
6. Mafauzy M. Diabetes Control and Complications in Public Hospitals in Malaysia. Med J Malaysia 2006; 61: 477-83.
7. WHO-5 weel-being index. http://www.cure4you.dk/354/WHO-5_English.pdf (accessed Aug 2010).
8. Alberti G. The DAWN (Diabetes Attitudes, Wishes, and Needs) study. Pract Diabetes Int 2002; 19: 22-24.
9. BIO-RAD, D10- Hemoglobin A1c Program, Instruction Manual.
10. National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation 2002;106: 3143-421.
11. Zaher ZM *et al*. Optimal cut-off levels to define obesity: body mass index and waist circumference, and their relationship to cardiovascular disease, dyslipidaemia, hypertension and diabetes in Malaysia. Asia Pac J Clin Nutr 2009; 18: 209-16.
12. Duerenberg P, Yap M, Van Staveren WA. Body mass index and percent body fat: a meta-analysis among different ethnic groups. International J Obes Relat Metab Disord 1988; 22: 1164-71.
13. Zhu S, Heymsfield SB, Toyoshima H, Wang Z, Pietrobelli A, Heshka S. Race-ethnicity–specific waist circumference cutoffs for identifying cardiovascular disease risk factors Am J Clin Nutr 2005; 81: 409-15.
14. Leiter LA, Ceriello A, Davidson JA, Hanefeld M, Monnier L, Owens DR, Tajima N, Tuomilehto J; International Prandial Glucose Regulation Study Group. Postprandial glucose regulation: new data and new implications. Clin Ther 2005; 27 Suppl B: S42-56.
15. Yu PC, Bosnyak Z, Ceriello A. The importance of glycated haemoglobin (HbA(1c)) and postprandial glucose (PPG) control on cardiovascular outcomes in patients with type 2 diabetes. Diabetes Res Clin Pract 2010; 89: 1-9.
16. Nitiyanant W *et al*. The Diabcare-Asia 1998 Study – Outcomes on Control and Complications in Type 1 and Type 2 Diabetic Patients. Curr Med Res Opin 2002; 18(5): 317-27.
17. Chaung LM *et al*. Comparisons of the outcomes on control, type of management and complications status in early onset and late onset type 2 diabetes in Asia. Diab Res Clin Pract 2006; 71: 146-55.
18. Clinical Practice Guidelines on Management of Type 2 Diabetes Mellitus, 4th edition, May 2009: MOH/P/PAK/184.09 (GU). Link: http://www.diabetes.org.my/file_dir/10233255764a4c4d7f8ad0e.pdf (Accessed 01 Sept 2010).