

## Standards of care in managing patients with type 2 diabetes in an outpatient clinic in tertiary care center in Sri Lanka.

Arambewela MH<sup>1,3</sup>, Somasundaram N<sup>1</sup>, Fernando KRAS<sup>1</sup>, Jayasena PM<sup>1</sup>, Chandrasekara CMPH<sup>1</sup>, Kusumsiri DP<sup>1</sup>, Jayasekara HABPR<sup>2</sup>, Kumbukage M<sup>2</sup>

<sup>1</sup>Endocrine and diabetes unit, National Hospital Sri Lanka.

<sup>2</sup>Ministry of health, Sri Lanka.

<sup>3</sup>Faculty of Medical Sciences, University of Sri Jayewardenepura.

### Abstract

**Background and objectives:** T2DM is a fast-growing problem in Sri Lanka. Evaluating the service provided to these patients is important to improve the care plan. Therefore, we aimed to audit the standard of care given to these patients.

**Methods:** A descriptive cross-sectional study among 3,000 patients with T2DM attending the diabetic clinic at National Hospital Sri Lanka from January to July 2016 was performed.

**Results and conclusions:** Monitoring of the blood pressure (BP), body mass index (BMI), HBA1c and lipid profile were performed in 95.8%, 96.5%, 59.6% and 42.3% respectively while none of the patients had waist circumference measured. Screening for retinopathy, diabetic foot was done in 89.3% and 99.9% respectively while screening for microalbumin in patients with normoalbuminuria was only in 31.2%. Mean HBA1c  $8.3 \pm 2.5$  %, SBP  $130 \pm 19.5$  mmHg, BMI  $26.6 \pm 4.6$  kg/m<sup>2</sup>, LDL  $99.78 \pm 23.75$  mg/dl, HDL  $46.93 \pm 10.52$  mg/dl and TG  $127 \pm 42.34$  mg/dl were comparable with metabolic parameters in other countries in the region. Only 24.3% of young diabetics without co morbidities, 29.3% of elderly diabetics with co morbidities and 22% of the rest of the diabetics achieved glycemic targets. Prescription rates of metformin, sulphonylureas, pioglitazone, DPP4 inhibitors and insulin were 90.8%, 58.8%, 0.6%, 11.9% and 26.9% respectively while none of the patients were on GLP-1 agonists or SGLT2 inhibitors. Among the patients with very poor glycemic control (HBA1c > 10.9%) 9.1% were on mono therapy and 71.3% were on dual therapy for glycemic control while only 56.7% were on insulin.

**Conclusion:** Screening for metabolic parameters and complications were high while measuring HBA1c, lipid profiles and nephropathy needs to be improved. Measuring waist circumference and screening for psychosocial issues need to be incorporated in the care plan. The majority of patients were on state funded anti diabetic agents. Doctors should be made aware of better strategies in improving glycemic care among patients with poor glycemic control.

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Correspondence e-mail: [maulee\\_80@yahoo.com](mailto:maulee_80@yahoo.com)



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## Introduction

The world in general and Asia in particular is currently facing an epidemic of diabetes. Combating diabetes has become one of the biggest challenges in the 21<sup>st</sup> century. Statistics in 2006 have revealed that one in five adults in Sri Lanka were diabetic or pre-diabetic with one-third of those being undiagnosed (1). Diabetes is a chronic disease with many long-term micro and macrovascular complications causing heavy morbidity and mortality. It is one of the leading causes of end stage renal disease, non-traumatic lower limb amputations, blindness and coronary heart disease, thus draining a larger portion of the national health budget. Management of a patient with diabetes should target a multifaceted approach focusing beyond the controlling of hyperglycemia but also reducing an individual's cardiovascular risk taking other important factors such as blood pressure, lipids, weight and life style into consideration. This important fact as well as early detection of micro and macrovascular complications is crucial in order to take timely actions and reduce long term cost of morbidity.

Even though standard guidelines on the systematic management of patients with diabetes are widely available adherence to these and achieving standards in care in an overcrowded outpatient clinic setting is often challenging. Lack of man power, infrastructure and equipment are some of the obstacles faced when caring for the patients with diabetes. In Sri Lanka, these patients are followed up in dedicated clinics for diabetes or in general medical clinics. Evaluating the care, we provide in these clinics and the standards we achieve is important in order to improve the present state of care. Since the origination of this clinic dedicated for diabetes in 2006 a comprehensive audit analysis has not been performed. Therefore, we set out to carry out an audit to find out the standard of care provided to the patients with type 2 diabetes at this specialized clinic at National Hospital of Sri Lanka.

## Methods

National Hospital is the biggest hospital in Sri Lanka with a bed strength of more than 3000. Around 16000 patients are registered in the diabetes clinic and around 400 patients a day attend the clinic to seek care. It is a tertiary care referral center and caters mainly to diabetic patients in Colombo and its suburbs. This descriptive cross-sectional study was carried out at the National Hospital Sri Lanka during the time period of 1<sup>st</sup> of January to 31<sup>st</sup> of July 2016. A total of 3000 consecutive patients with type 2 diabetes undergoing annual end organ screening were

systematically sampled. Patients who had been followed up in the diabetic clinic for at least 1 year were included. Pregnant patients and type 1 diabetics were excluded.

Data was extracted from the patients' clinic records by medical officers in the diabetic clinic following reviewing the most updated measurements, investigations and management recorded in individual clinic books. These measurements included blood pressure, Body mass index (BMI), lipid profile, HBA1c, retinopathy screening via retinoscope, foot examination via specially trained medical officers, and nephropathy screening via urine full report for macroalbumin and looking for microalbumin in patients with normoalbuminuria with urine for microalbumin creatinine ratios and screening of macrovascular disease with 12 lead electrocardiogram (ECG). The latest most measurement was recorded and the current medication obtained to calculate the treatment goals and management practices respectively. Treatment goals were in accordance with the goals laid down by the college of Endocrinologists in Sri Lankan on the management of glucose control and cardiovascular disease (CVD) risk reduction in diabetes (2, 3).

## Ethical issues

Ethical clearance was obtained from the ethical review committee of the University of Colombo prior to initiation of the study. Administrative approval was obtained from the hospital representatives. Participation was entirely voluntary and written informed consent was obtained from the participants.

## Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) version 20. Frequencies of all variables were analyzed using descriptive statistics. Data was reported as mean  $\pm$  SD and percentages.

## Results

Out of the three thousand patients studied in this patient population, 2180 were females (72.7%) and 820 (27.3%) were males. Mean age  $\pm$  SD was 58.3  $\pm$  10.3 years. Mean duration of diabetes  $\pm$  SD was 10.8  $\pm$  7.3 years.

Table 1 displays the prevalence of measurement of blood pressure, BMI, waist hip ratio, HBA1c and lipid profile recorded during the annual screening and the mean value in the study population for each parameter. Even though BMI was measured in 96.53% of the patients none of the

**Table 1: The prevalence of checking measurement and their mean values**

Measurement	Prevalence of measurement in the study sample (n=3000)	Mean value $\pm$ SD
<b>Blood pressure</b>	2875 (95.8%)	SBP 130 $\pm$ 19.9 mmHg DBP 79.4 $\pm$ 10.3
<b>BMI</b>	2896 (96.5%)	26.6 $\pm$ 4.6
<b>Waist circumference</b>	0%	
<b>HBA1c</b>	1790 (59.6%)	8.3 $\pm$ 2.5 %
<b>Total cholesterol</b>	2072 (69.0%)	167.69 $\pm$ 43.89 mg/dl
<b>Low density lipid profile (LDL)</b>	1271 (42.3%)	99.78 $\pm$ 23.75 mg/dl
<b>High density lipid profile (HDL)</b>	1271 (42.3%)	46.93 $\pm$ 10.52 mg/dl
<b>Triglyceride (TG)</b>	1271 (42.3%)	127.92 $\pm$ 42.34 mg/dl

**Table 2: The prevalence of screening for complication**

Complication	Prevalence
<b>Retinopathy screening</b>	2679 (89.3%)
<b>Foot examination</b>	
Measurement of Ankle Brachial Pressure Index	2998 (99.9%)
Measurement of touch sensation with monofilament	2915 (97.1%)
Measurement of vibration sensation	2912 (97.0%)
<b>Nephropathy screening</b>	
Screening for macro albuminuria with urine full report	2372 (79.0%)
Screening for microalbuminuria in patients with normo albuminuria	647 (31.2%)
Evaluating estimated glomerular filtration rate	2481 (82.8%)
Screening for macrovascular complications	2908 (96.9%)

patients had waist circumference checked. Prevalence of screening for complications is demonstrated in Table 2.

Screening for retinopathy, neuropathy, and macrovascular disease was high in the population except for detection of albuminuria. Achievement of goals in glycemic control, blood pressure, lipids and BMI are illustrated in table 3.

Less than one fourth of the middle-aged patients with chronic diabetes, without any major co morbidities had a HBA1c of less than 7%. Only 24, 3% of the young diabetics with a disease duration of less than 5 years and without any significant morbidity fulfilled the more stringent HBA1c criteria of <6.5%. Blood pressure control was more satisfactory with 77.1% achieving targets. Less than one fourth of the population had ideal

BMI of <23 highlighting the burden of obesity among diabetics. Table 4 compares metabolic parameters of this patient population with the other regions in the Asian subcontinent.

Prescription preference for antidiabetic medication in decreasing order was metformin (90.8%), sulphonylurea (58.8%), Insulin (26.9%), DPP4 inhibitors (11.9%), Acarbose (1.2%) and Pioglitazone (0.6%), while none of the patients were on GLP1 agonists or SGLT2 inhibitors (Figure 1).

Among the patients with very poor glycemic control (HBA1c >10), 9.1% were on monotherapy and only 56.7% were on Insulin. 16.6% of patients with moderate glycemic control (HBA1c 7-10%) were on monotherapy. (Table 5)

**Table 3: Achievement of goals in standards of care**

Goals in standards of care	Percentage achieved in study sample
HBA1c <7% among patients aged 45-65 with >5 years of disease and no significant morbidity	163 (22%)
HBA1c<6.5% among diabetics <45 years with disease duration <5 years and no significant cardiac /renal disease	17 (24.3%)
HBA1c 7-8% among elderly (age >65)	118 (29%)
BP <140/90	2219 (77.1%)
BMI <23	704 (24.3%)
LDL <100 mg/dl	743 (58.4%)
TG <150 mg/dl	942 (74.1%)
HDL >50 mg/dl in females	360 (39.0%)
HDL>40 mg/dl in males	218 (62.4%)
Non-smoking among males	734 (89%)
Non-smoking among females	2140 (98.4%)

**Table 4: Comparison of metabolic parameters with other regions**

Parameter	Sri Lanka	South Asia	East Asia	Middle East
HBA1c	8.3%	9.3%	9.7%	9.7%
BMI	26.6	26.1	25.0	30.9
SBP	130 mmHg	145 mmHg	133 mmHg	141 mmHg
Total Cholesterol	167 mg/dl	201 mg/dl	204 mg/dl	208 mg/dl
LDL	99 mg/dl	131mg/dl	131 mg/dl	123 mg/dl
HDL	46 mg/dl	38 mg/dl	46 mg/dl	38 mg/dl
TG	127 mg/dl	194 mg/dl	177 mg/dl	203 mg/dl

\*Data from other regions taken from a multinational study done from 2009-2010

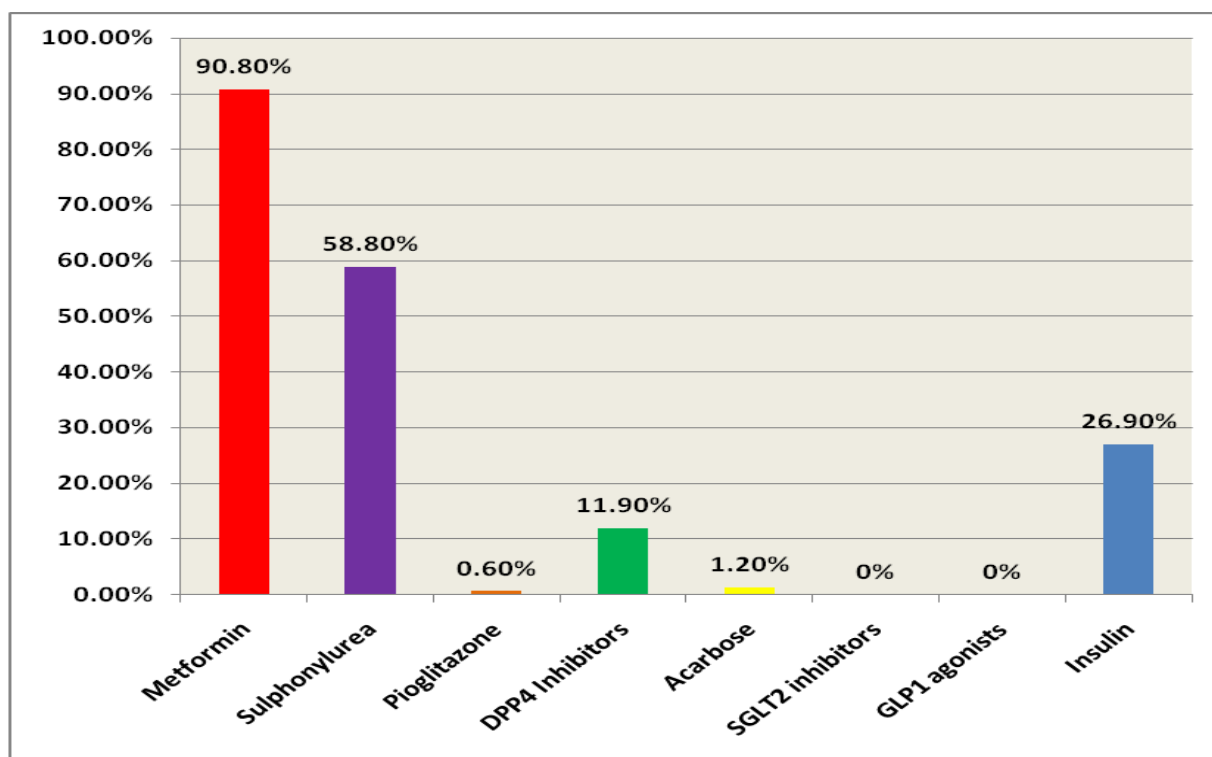


Figure 1: Prescription of antidiabetic medication

**Table 5: Relationship between glycaemic control and anti-diabetic medications**

Management practice	Percentage
Metformin on patients with GFR >30 ml/min/1.73 m <sup>2</sup>	2394 (91.8%)
Statins on patients >40 years of age	2743 (90.8%)
Statins on patients with CVD	274 (89.3%)
ACEI/ARB in patients with hypertension	1998 (90.2%)
ACEI/ARB in patients with nephropathy	328 (71.8%)
Antiplatelet in secondary prevention	207 (67.2%)
Antiplatelet in primary prevention (patients >50yrs of age with at least 1 cardiovascular risk factor)	193 (40.3%)
Inquiry in to patient's psychosocial wellbeing by the treating doctor	399 (13.3%)

**Table 6: Treatment practices**

Anti-diabetic medications	Glycemic control		
	<7%	7-10%	>10%
Monotherapy	39.4%	16.6%	9.1%
Dual therapy	57.3%	68.1%	71.3%
Triple therapy	3.3%	14.9%	18.6%
Quadruple therapy	0%	0.4%	1.0%
Insulin injections	11%	28.4%	56.7%

### Discussion

Conducting an audit is an important element in the process of patient care. It gives an opportunity to self-evaluate the services provided and highlights suboptimal areas that have the potential for improvement. Screening for outcome measures of blood pressure and BMI were high at the annual end organ evaluation with a prevalence of 95.83% and 96.53% respectively.

Blood pressure and weight are two parameters that are being checked at each clinic visit, which probably is the reason for high screening rates in these patients.

Obesity among Sri Lankans is an important health hazard which is increasing at an alarming pace. Abdominal obesity has demonstrated a better correlation with hypertension, dyslipidemia, diabetes and atherosclerotic CVD than BMI in Asian populations (5). The mean BMI value recorded

was 26, which according to Sri Lanka cut offs is in the category of obese class I (4). Although abdominal obesity is more relevant to our patient population, none of the patients at the diabetic clinic have had this measurement. This highlights a deficit in care and should be incorporated in to the annual screening program.

According to the Sri Lanka College of Endocrinologists guidelines on glucose control in diabetes mellitus, it is recommended to assess the glycemic control with HBA1c measurement at least once in 6 months in patients with stable glycemic control and once in 3 months when glycemic control is poor (2). However, it was measured in only 59.66% and was mainly due to the limited availability of this investigation in our hospital. NHSL is the main tertiary care referral center in the country and it is vital that laboratory facilities are improved to meet these basic demands in order to optimize care of these patients.

Lipid profile is an important parameter that is considered in the assessment of the CVD risk of an individual and to take decisions on CVD prevention interventions. However, in the presence of diabetes and associated high cardiovascular risk, CVD risk calculation has a limited role and local and most of the international including ADA 2017 guidelines recommend the use of statin for all the patients more than 40 years (3, 6). The strength of the dose of statin is determined by the individual's 10-year cardiovascular risk, which could be calculated by atherosclerotic cardiovascular disease (ASCVD) risk calculators. It is recommended to have a baseline lipid profile at the time of diagnosis of diabetes and at least every 5 years thereafter for adults with type 2 diabetes (6). However, a significant proportion of patients (42.36%) in the diabetic clinic underwent a lipid profile during the annual screening. Our patients may not need that many lipid profile measurements and it may be useful to have local protocol to guide the medical officers to utilize the laboratory facilities in a cost-effective manner without undue overburden.

A very high proportion of patients had screening for diabetes complications and the screening rates for retinopathy, foot disease and nephropathy using macroalbuminuria were 89.31%, 99.93% and 79.06% respectively. The diabetic clinic at NHSL runs a well-organized end organ screening program for patients with diabetes and a large number of patients with diabetes who are followed up in other clinics in the hospital as well as suburban clinics are referred here for annual screening for end organ diseases. However, these high screening rates are obviously due to the sample bias as all these patients were selected from the patients who were undergoing annual end

organ screening. It is of note that screening for nephropathy, especially in detecting urine for microalbumin (31.21%) is comparatively lower due to the limited availability of this test.

Local and international guidelines recommend a personalized approach to glycemic control and 7% is often used as the HbA1C target (2,6). Despite the comprehensive management guidelines and the availability of a variety of therapeutic options, many patients around the world continue to have inadequate control. A National Health and Nutrition Examination Survey (NHANES) done between 2007-2010 in the United States of America has demonstrated that 48% of patients with diabetes had HBA1c of >7% and 13% of the patients having a HBA1c of >9% (7). In an audit of over 2 million patients with diabetes in England and Wales has also shown similar findings where 35% of patients with T2DM had HbA<sub>1c</sub> >7.5% (8). Our audit paints an even more disheartening picture with HBA1c targets of <7% achieved in only 22% of the diabetic population. A large study done in 2009-2010 enrolling patients with diabetes from 28 countries in 4 continents on baseline metabolic control showed comparable results (9). The comparison with our data is highlighted in Table 4. These data suggest that despite all efforts in formulating guidelines and newer treatment modalities, diabetes is still an inadequately controlled disease.

The discrepancies in the achievement of glycemic targets are attributed to the standards in quality of life, awareness regarding the disease and the availability to the wide array of newer and more advanced anti hyperglycemic agents. This fact is even more consolidated when looking in to the prescription patterns depicted in Figure 1. Being a state-run institution, the majority of the patients in our clinic are on metformin, sulphonylurea and insulin which are provided free of charge to the patients. 11.9% of patients were on DPP4 inhibitors as a result of a donation of this medication to clinic patients during the study period. None of the patients were on the newer therapeutic modalities such as GLP1 agonists or SGLT2 inhibitors. This is mainly due to the high cost and unavailability of these medications.

It is interesting to note that prescription of pioglitazone is seen only among 0.6%. The long-term argument of its probable association with bladder cancer is most likely the culprit for the underutilization of this drug. However, a recent meta-analysis has concluded that this hypothetical risk should be attributable to other factors and that there is no eligible reason for diabetic patients not to explicit

the benefits of this medication (10). Considering its efficacy of HBA1c reduction, favorable effect on atherosclerosis and the lower cost, it may be a worthwhile considering this therapeutic option in targeted patients.

It is important to note that 9% of the patients with very poor glycemic control (HBA1c>10%) and 16.6% of patients with moderate glycemic control (HBA1c 7-10%) are still on mono therapy. According to both local and international guidelines, patients who do not achieve glycemic targets within three months of monotherapy should be commenced on another antidiabetic agent with a different modality of action. Another important fact was that 43.3% of patients with very poor glycemic control of HBA1c >10% were not on insulin. This may be partially attributed to the great reluctance among our patients to commence injectables. However, both these facts highlight the deficiencies in addressing patient and physician factors that influence the glycemic control and the necessity to take steps to overcome these issues.

Prescription of metformin and statins in accordance with guidelines was satisfactory. 91.8% of the patients with GFR>30% were on metformin and 90.8% of patients over the age of 40 years and 89.3% of patients with CVD were on statins. Usage of ACEI/ARB among diabetic patients with hypertension is also commendable. However, in comparison anti platelet therapy in primary and secondary prevention is 40.3% and 67.2% respectively. This may probably be due to the associated gastric irritation with anti-platelet agents such as aspirin.

Worldwide, the prevalence of mood and anxiety disorders is higher among patients with diabetes compared to those without diabetes. In a meta-analysis of 42 published studies comprised of 21,351 adults, the prevalence of

major depression in people with diabetes was 11% and the prevalence of clinically relevant depression was 31%(11). The 2017 ADA guidelines on standards of care in diabetes recognizes the importance in evaluating patients with this chronic medical illness for anxiety and depression. Evaluation of psychosocial wellbeing is an important component in providing holistic care. However, only 13.3 % of patients commented that treating doctors have ever inquired to their psychosocial well-being and reflects the inadequate time spent for evaluation of these psychosocial issues.

### Limitation

There were several limitations in this study. Selecting the sample group from patients who were undergoing annual target organ screening gave rise to a selection bias. Furthermore, this study did not assess the dietary and life style parameters which plays an important role in patients suffering from this chronic non-communicable disease.

### Conclusion

This audit has revealed our diabetes care has been able to provide metabolic screening and screening for end organ complications to a satisfactory level, which is an important aspect of diabetes management. Except for anti-platelet agents, our adherence to guideline on prescription of metformin, statins, ACEI/ARB has been high. However, the achievements related to the metabolic targets were poor and comparable with other countries in the region. This being the most important aspect of diabetes management in the prevention of related complications needs more attention and highlights the need to find new strategies overcome this problem.

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