Study Title

Evaluating adherence to recommended clinical guidelines for the prevention of cardiovascular disease in patients with Type 2 diabetes mellitus at primary care level.

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1. Preamble

Declaration

1.1 Declaration

DECLARATION

I, William Langerhove, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abstract (words: 249)

Background

Globally, type 2 diabetes (T2D) is a significant cause of avoidable mortality and morbidity. It is a major risk factor for cardiovascular disease (CVD). Evidence-based guidelines lower cardiovascular risk in diabetics. Adherence to clinical guidelines for the prevention of CVD in South African primary care public sector facilities is unknown.

Aim

This study determined adherence of Cape Town primary care clinicians to recommended clinical guidelines for the prevention of cardiovascular disease in T2D.

Methods

This 2013 cross-sectional study extracted data from 300 folders of known T2D patients sampled from three Community Health Centres (CHCs). Compliance with guidelines, and patient demographic factors were analysed.

Results

Most (71% or 194/273) hypertensive diabetics were appropriately managed with first-line-medication - an Angiotensin Converting Enzyme Inhibitor (ACEI). There was appropriate supporting documentation for only 39% not on first line therapy. A fifth (22%) with drug intolerance received the recommended alternative. Most were appropriately prescribed a statin (74%) and aspirin (69%). Other cardiovascular risk factors were poorly controlled: mean weights were in the obese range (BMI=31.3 [SD: 5.7]); the mean total cholesterol level was 5.5 (SD: 1.4); there was incomplete data for smoking (19% had no record) and 93% had no record of a family history of CVD.

Conclusions

Whilst pharmacological interventions for the prevention of CVD were moderately implemented, patient factors – such as obesity and smoking were poorly addressed. Improving documentation, adherence to recommended clinical guidelines and, health promotion to address modifiable risks are required to improve quality of care for T2D.

Keywords: diabetes, cardiovascular risk, adherence, guidelines, Angiotensin Converting Enzyme Inhibitor (ACEI), statin, aspirin, Angiotensin Receptor Blocker (ARB)

List of Abbreviations

ACEI	angiotensin-converting enzyme inhibitor
ARB	angiotensin receptor blocker
BMI	Body Mass Index
CHC	Community Health Centre
CNP	Clinical Nurse Practitioner
CVD	cardiovascular disease
DALY	disability-adjusted life year
HTN	hypertension
IHD	ischaemic heart disease
PHC	primary health care
MDHS	Metro District Health Services
MI	myocardial infarction
SEMDSA	Society for Endocrinology, Metabolism and Diabetes of South Africa
T2DM	Type 2 Diabetes Mellitus
USA	United States of America
WHO	World Health Organization
YLD	years of life lived with disabilities
YLL	years of life lost

2. Protocol

Overview:

1. Study Title
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Study title

Evaluating adherence to recommended clinical guidelines for the prevention of cardiovascular disease in patients with Type 2 diabetes mellitus at primary care level.

Background and motivation

Diabetes is a growing problem worldwide, including in Africa. Hall et al[1] conducted a systematic review of papers published on diabetes in Sub-Saharan Africa from 1999 to 2011. They collected data on prevalence, complications, mortality and economic burden. The recorded population prevalence of Type 2 diabetes varied between countries, ranging from 1% in rural parts of Uganda to 12% in urban Kenya. Patients with diabetes showed 5-year mortality rates ranging from 4%-57%. Type 2 diabetes (T2DM) accounted for more than 90% of diabetes in Sub-Saharan Africa[1].

T2DM can remain undetected for many years, and is often only diagnosed after incidental blood or urine glucose testing. Diabetes has traditionally been defined by elevated blood glucose, and the management of diabetes has focussed on glucose control. However, it is well known to be an independent risk factor for cardiovascular disease, and is an important cause of the decrease in life expectancy of people with diabetes. Non-glycaemic factors are critically important in the management of diabetes, especially with regard to reducing the associated cardiovascular risk and its effects. [2] Lowering this risk involves using multiple approaches. Lifestyle modifications such as exercise, smoking cessation, dietary intervention and weight regulation are still vital aspects of diabetes management and prevention of CVD.

Motivation

Primary care plays a key role in the prevention and management of cardiovascular disease in high risk patients such as diabetics. Most diabetics are managed at a primary care level in the public healthcare system, and the Metro District Health Services (MDHS) oversees primary healthcare services in the Cape Town area through a network of CHCs. Facilities serve mainly the uninsured, but also attend to patients on various medical aid schemes and funds. Patients are attended to by doctors and clinical nurse practitioners (CNPs). Patients attend monthly to receive their medication. The frequency of doctor/CNP visits will depend on how well the condition is controlled. Follow-up visits for chronic conditions like diabetes are usually 3-6 monthly. Generally, the CHCs have been perceived to deliver a substandard level of care for chronic illnesses, including T2DM, as was found in two studies. In 1992, Levitt et al[3] audited 3 CHCs in Cape Town known to have high numbers of diabetic patients. They

looked at the level of control of blood sugar and blood pressure, and also the prevalence of complications related to diabetes. They found control to be poor- only 38% of patients had a normal blood pressure, and 49% had acceptable blood sugar control. There was also a high prevalence of complications, such as retinopathy, cataracts, peripheral neuropathy, peripheral vascular disease, amputations and kidney disease. They concluded that secondary prevention was not being adequately practiced as part of the management of diabetes. They suggested that the introduction of clinical guidelines would do much to improve health outcomes and reduce the prevalence of complications. The second study, conducted in 1999, Steyn et al[4] investigated diabetic and hypertensive control at a sample of CHCs in the Cape Town area. The data showed poor levels of control for these two diseases.

Service audits have been introduced in MDHS services to address quality of care, including chronic diseases care. The first, conducted in 2008 at 15 CHCs within MDHS , followed accepted guidelines to assess clinical practice, the SEMDSA guidelines. They recommend that diabetics are reviewed in detail at least once annually, and this is known as the diabetic annual review.[5]

SEMDSA provides nationally accepted clinical guidelines[6] for the management of T2DM, which are distributed to clinical staff at CHCs within the MDHS. The diabetic annual review involves a number of tests and examinations which should be performed- some annually (e.g. visual acuity and dilated eye exam, foot exam, creatinine and lipid profile), and others more frequently (quarterly- HBA1C, or twice yearly if stable).

The investigators demonstrated significant shortcomings in the level of care provided. This was reported to MDHS, and resulted in key changes being made to improve the care of diabetic patients. This inadequacy in the clinical management of diabetes is not limited to our setting. Brown et al[7] conducted a study amongst family practitioners in Ontario, Canada. Similar parameters were measured, and compared to their recommended clinical guidelines. The results also showed a suboptimal level of clinical care for diabetics in that setting, with poor adherence to clinical guidelines by clinicians.

Overview of the literature

Epidemiology

According to the World Health Organization (WHO), most deaths worldwide are caused by non-communicable diseases[8]. Burden of disease studies measure the health impact that

different diseases have on countries. The burden due to premature mortality is reflected as years of life lost (YLL), and the health burden due to morbidity (illness or injury) is reflected as years lived with disability (YLD). These two parameters are used to calculate disability-adjusted life years (DALY) for specific causes. One can then determine the burden of different diseases, and then use the results to guide public health action.

Green et al[10] examined epidemiological data to find global prevalence estimates for Type 2 Diabetes Mellitus (T2DM) for the year 2000 and then projections for 2030. It was calculated that the number of people with diabetes would double during that period. Sub-Saharan Africa, along with other developing regions, is expected to have the greatest increases in the number of people with diabetes.

These findings indicate that diabetes will become an epidemic of global proportions, not only of developed countries. Risk factors for developing diabetes which linked to this are increasing obesity levels, inactivity, ageing populations and urbanization with its associated lifestyle and dietary changes.[11]

Burden of disease for diabetes in South Africa

Bradshaw et al[9] investigated the burden of disease as a result of diabetes in South Africa in the year 2000. The burden attributable to diabetes was found to be unacceptably high. The outcomes assessed were the DALYs for ischaemic heart disease (IHD), stroke, hypertensive disease and kidney disease. The estimated prevalence of diabetes in South Africans over the age of 30 years was found to be 5.5%, and increased with age. The results showed diabetes to be responsible for 4.3% of all deaths in South Africa in 2000. Diabetes was associated with 14% of IHD, 10% of stroke, 12% of hypertensive disease and 12% of kidney disease burden.

In 1996 Levitt et al[12] conducted a cross-sectional descriptive study in Mamre, a small town 55km from central Cape Town. The aim was to assess the prevalence of T2DM in this peri-urban, mainly ‘mixed race’, known as ‘coloured’ working-class community. The age-standardised prevalence of T2DM in the 30-65 years’ age group was 10.8%. Since then South Africa has undergone major changes in many areas. In 2008 Erasmus et al[13] performed a cross-sectional study in Bellville South, Cape Town in order to determine the prevalence of diabetes in an urban community. This is also a mainly coloured populated area. The study also targeted subjects over the age of 30 years. They found a high prevalence of T2DM (28%) in this area. This shows a substantial increase in the prevalence of diabetes in the

coloured population. These results indicate that diabetes is a significant public health problem.

Complications of T2DM - Cardiovascular risk

There is ample evidence showing that T2DM is associated with a markedly increased CVD risk.[14, 15] This has major public health repercussions, and will worsen with the projected increased incidence of diabetes. The Framingham Study,[14] a prospective study over 20 years found the incidence of CVD in diabetic men to be twice that of nondiabetic men. In diabetic women the incidence of CVD was three times higher than in nondiabetic women. In a seven-year Finnish study, after controlling for cardiovascular risk factors such as smoking, hypertension and lipid abnormalities, Haffner, et al [15] showed that diabetics had an equivalent risk for a myocardial infarction (MI) to that of non-diabetics with previous MI. They found that both groups were at increased risk for MI, and that the risk was similar for the two groups. They conclude from their findings that diabetics should be managed as if they have had prior CVD, and their cardiovascular risk factors should therefore be managed as aggressively as nondiabetics with known CVD. These findings were also supported by a study in Scotland, where subjects were followed over 25 years.[16] They showed that diabetics have a lifetime cardiovascular mortality risk similar to that of nondiabetics with CVD.

Haffner, et al[17] performed a prospective cohort study among female nurses (who were free of known CVD) over a period of 20 years. They investigated the risk of MI in subjects and found that even during this pre-diabetic period (before being diagnosed with diabetes) there was a significantly higher risk of MI, as compared to the subjects who remained nondiabetic during the course of the study. The conclusions therefore are that both prediabetes and diabetes confer to the patient a higher CVD risk profile, and once there was clinical CVD, then the prognosis is even poorer. We should therefore do as much as we can to minimise this cardiovascular risk as much as possible.

Guidelines

The Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) guidelines[6] are accepted nationally as evidence-based, and are applicable to the healthcare setting at a primary care level. These guidelines recommend the following actions for reducing CVD risk in Type 2 diabetics:

Blood Pressure Treatment

An angiotensin-converting enzyme inhibitor (ACEI) should be the drug of choice as first-line therapy. Enalapril is the ACEI currently available in the MDHS. In case of ACEI-intolerance, an angiotensin receptor blocker (ARB) should be prescribed. Losartan is available- but its prescription needs to be initiated by a specialist physician.

Lipid Treatment

A statin should be prescribed for all Type 2 diabetics, regardless of baseline lipid levels: as primary prevention for those over 40 years with CVD risk factors, or secondary prevention if established CVD. Simvastatin is used in our setting, and can be initiated by a primary care doctor.

Antiplatelet Agents

(150mg/day) should be prescribed for all Type 2 diabetics: as primary prevention for those over 40 years or have CVD risk factors, or as secondary prevention for those with known CVD.

The evidence for the above recommendations is outlined below.

Blood Pressure

According to the South African Hypertension Guidelines 2011,[18] blood pressure targets are stricter for diabetics: systolic <130mmHg and diastolic <80mmHg, compared to targets of systolic <140mmHg and diastolic <90mmHg for a non-diabetic. Campbell et al[19] investigated the management of diabetics with hypertension. They performed a systematic review of the literature on hypertension and diabetes. They found that hypertension commonly co-exists with diabetes- the pathogenesis of this is complex and multifactorial, and that this imparts a higher risk for CVD. Controlling the blood pressure has been shown in several trials to effectively reduce the associated cardiovascular morbidity and mortality. The HOPE study[20] showed that treating hypertensive diabetic subjects with the ACEI Ramipril was associated with a significant reduction in cardiovascular events. The ACEI effect was actually found to be independent of its effect on the blood pressure. The CAPPP (Captopril Prevention Project) trial used captopril to assess the effect on cardiovascular risk in diabetics with hypertension.[21] Compared with a diuretic and/or B-blocker regimen,captopril was shown to significantly reduce fatal and nonfatal cardiovascular events. Fatal cardiovascular events were reduced by

half. Studies using perindopril-based regimens[22] also demonstrated cardiovascular protection for hypertensive diabetics.

These studies therefore support the utilisation of ACEI-based regimens in the management of hypertension in the diabetic patient, in the drive to reduce cardiovascular risk.

Lipids

The Heart Protection Study[23] compared simvastatin 40mg daily with placebo in randomly allocated diabetic subjects, and other individuals at high risk of vascular events. There was on average a 1.0mmol/L reduction of LDL-cholesterol levels in the simvastatin group, over the 5-year study period. The subjects allocated to the simvastatin group experienced about a 25% reduction in a first major vascular event. Cardiovascular risk reduction occurred both in the presence and absence of established coronary artery disease. There were also significant reductions in subsequent vascular events. These beneficial effects were found, regardless of the subjects' baseline lipid levels. The authors recommend that all diabetics who are at sufficiently high risk of vascular events should be considered for statin treatment, regardless of baseline lipid levels. The LIPID trial[24] showed that pravastatin produced beneficial effects on cardiovascular risk, as the risk of a cardiovascular event was significantly reduced. The American Diabetes Association recommends that all diabetic patients should receive statin therapy: as secondary prevention for those with established CVD, and as primary prevention for those diabetics without known CVD, but over the age of 40 years and with one or more CVD risk factor.[25]

Statins have therefore been shown to be instrumental in the drive to reduce cardiovascular risk in diabetic patients, and their use in these patients is recommended by authorities on the subject.

Antiplatelet agents

Acute ischaemic coronary events are mainly precipitated by thrombosis,[26] and this is the mechanism of CVD in diabetics. Antiplatelet agents such as aspirin have been shown to be a key element of thrombosis prevention in individuals at high risk of thrombotic events. This was confirmed in meta-analyses performed by the Antithrombotic Trialists Collaboration,[27] where aspirin use was associated with a reduction in serious vascular events. The SEMDSA guidelines[6] recommend that aspirin treatment should be provided for those diabetics with a history of prior CVD, or those with increased cardiovascular risk. This includes diabetics

over the age of 40, and those with additional risk factors, e.g. hypertension, smoking, dyslipidaemia and a family history of CVD.

Adherence to guidelines

Several studies have been performed to investigate adherence to clinical guidelines for the prevention of CVD in diabetics. The results varied widely, ranging from about 20% to about 90%[28,29,30] levels of adherence. The introduction of evidence-based clinical guidelines to change prescribing habits has been shown to reduce healthcare costs.[31] Evidence-based clinical guidelines should therefore form the basis for the provision of good medical care. It is obvious that the prescribing habits of clinicians will directly impact on the cost of healthcare. However, the availability of guidelines does not necessarily lead to their application. In an environment with limited resources such as ours, cost should therefore factor into our prescribing habits. In practice, the obstacles are the dissemination of the guidelines, and then also the application by clinicians. What happens in our CHCs?

Impact of the findings on practice

Type 2 Diabetes is common and the incidence is increasing. With rising obesity rates worldwide, this trend is set to continue, and there is concern that it will reach epidemic proportions. Diabetes has major public health and economic impacts, and managing the disease and its complications is expensive.

The level of adherence to recommended clinical guidelines impacts on quality and cost of care. So too can the extent to which they are made available at the facilities. With local studies showing poor control of chronic diseases and high prevalence of complications at primary care level, it will be useful to know what the level of adherence is to accepted guidelines for the prevention of morbidity and mortality from cardiovascular disease. A study that elucidates this would fill this gap and findings provided to clinicians and management, could inform improved practice.

Study aims and objectives

Aims

The study aims to evaluate adherence to recommended clinical guidelines for the prevention of cardiovascular disease in Type 2 diabetics at a primary care level.

Objectives

A. Primary objectives

1. To describe the demographic characteristics of type 2 diabetic patients managed at primary care level in the MDHS.

2. To determine the proportion of type 2 diabetics treated at primary care settings in Cape Town who are appropriately managed to reduce cardiovascular risk, specifically with regard to:

a) Lipid treatment: are all Type 2 diabetics prescribed a statin, regardless of lipid levels.

b) Blood pressure treatment: An angiotensin-converting enzyme inhibitor (ACEI) as first-line treatment for diabetics with raised blood pressure.

c) Antithrombotic treatment: Low dose Aspirin (75-150mg daily)- as secondary prevention in all Type 2 diabetics with a history of CVD, or as primary prevention in those diabetics at higher risk, such as those over the age of 40 years, or those with additional CVD risk factors, e.g. hypertension, smoking, dyslipidaemia and a family history of CVD.

3. To compare CHCs regarding level of adherence to recommended clinical guidelines, and to assess factors associated with good adherence to guidelines.

B. Secondary objectives

To make recommendations regarding the implementation of clinical guidelines at Primary Care level to reduce cardiovascular risk in Type 2 diabetics based on the results of the study.

Study design, methodology, sampling and data analysis

Definitions:

Diabetic

A person who has diabetes, as classified by a PHC clinician.

Hypertension

Blood pressure: systolic <130mmHg and diastolic <80mmHg.

High risk

The patient has risk factors for CVD, e.g. hypertension, dyslipidaemia, smoking, obesity and a family history of IHD

Lipid treatment

The patient is (at the time of the study) receiving Simvastatin, a statin drug, at a dosage of at least 10mg daily.

Antithrombotic treatment

The patient is (at the time of the study) receiving Aspirin, an antiplatelet agent, at a dosage of 75-150mg daily.

Study design

The study design to be used is an observational cross-sectional study, which will review patient records, using patient medical records. The study will use existing data obtained from patient medical records.

Sampling

Source population:

Type 2 Diabetics attending 3 different CHCs in Cape Town for their chronic diabetic care. The 3 CHCs which will be used for the study are Hanover Park, Mitchells Plain and Retreat. These CHCs are known to have a heavy caseload of type 2 diabetic patients attending on a regular basis. However, as there are no registers at CHCs for chronic patients, there are no accurate figures available for the number of diabetics attending the CHCs.

Sampling frame

Attendees of the 3 CHCs who have previously been diagnosed with Type 2 diabetes, with at least 3 visits in the previous year.

Inclusion criteria

Age 40 years or older, being a documented attendee (a “club” patient), with at least 3 visits during the previous year for diabetes, and having received treatment for this condition at each visit.

Methods

Data collection

The data collection will be performed by the researcher. Permission to conduct research will be obtained from the facility Manager of each CHC. All patient records are filed and stored in the Records Department of each facility. Folders are filed according to their folder numbers. Folders of diabetics are not filed separately, but are marked with a sticker to distinguish them from other folders. Folders of diabetic patients will be retrieved and selected randomly (every second folder), and then filtered according to the inclusion criteria. The folders which fulfil the criteria will be reviewed for the following variables:

Parameters

Gender (male/female)

Age

Known diabetic: yes/no

Time since diagnosis of diabetes (years)

3 Attendance visits past year for diabetes: yes/no

cardiovascular risk factors recorded, e.g. HTN, smoking, family history of IHD, dyslipidaemia Known/unknown IHD

ACEI: yes/no

ASA: yes/no

Statin: yes/no

For each drug if "no", then is there a documented contra-indication or history of drug intolerance.

Sample size calculation

The sample size (n) is calculated according to the following formula:

$$n = \frac{p(1-p)z^2}{d^2}$$

p= anticipated population proportion (50%) of good adherence to clinical guidelines.

d= level of precision (10%)

z-score= 1.96

n = 96

Therefore 96 folders will be randomly sampled from each CHC.

Data analysis

Descriptive statistics will be provided for all variables. All data will be entered onto an Excel spreadsheet and analysed. Categorical data will be presented as frequencies and percentages in tables. The chi-squared test will be used to test the difference between observed and expected results. A p-value of <0.05 will be regarded as significant.

Timeline and budget

The anticipated timeline consists of the following phases:

1. Submission to ethics committee for approval: end of February 2013
2. Data collection: March- April 2013
3. Data analysis: May 2013
4. Completion and submission of research study: June2013.

The fieldwork for the study will be done by the investigator once ethics approval is obtained. There is no budget allocation. Any costs incurred will be borne by the researcher.

Ethical considerations and reporting of results

Ethical approval will be sought from the UCT Research Ethics Committee. Permission to conduct the study will be obtained from the MDHS and the facility managers at the relevant CHCs. There is no conflict of interest.

Non-maleficence

Data will be sourced from patient medical records, so patients will not be exposed to any risk.

Beneficence

The study aims to promote the well-being of patients by investigating whether evidence-based guidelines are being adhered to. Benefits of the research study will include making recommendations toward the improvement of healthcare at a primary care level.

Respect for Autonomy

All data will be collected from patient records. This information will be captured, analysed and then reported on without using any patient-identifying characteristics or personal information. This will ensure that patient confidentiality will be maintained.

Justice

In our setting, we struggle with scarce health resources. The study will promote cost-effective, evidence-based management of diabetic patients.

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Appendix:

Table 1. Data Capture Sheet

Name of CHC	Patient folder no.	Age	Sex	Known T2DM	3 visits in last year	HTN	IHD	ACEI prescribed	ACEI non-prescription justified	Statin prescribed	Statin non-prescription justified	ASA prescribed (if risk factor for CVD)	ASA prescribed without risk factor for CVD	ASA non-prescription justified	Smoke
1															
2															
3															
4															
5															
6															
7															
8															
9															

Data capture sheet continued:

Name of CHC	Obesity	Dyslipidaemia	Family history of CVD	Time since diagnosis <8years	>8years				
1									
2									
3									
4									
5									
6									
7									

Table 2. Demographic characteristics

FACTOR	CASES (%)
1. SEX	
Male	
Female	
2. AGE	
30-39	
40-49	
50-59	
60+	

Table 3. Prevalence of Cardiovascular risk factors

CARDIOVASCULAR RISK FACTORS	CASES (%)
Hypertension	
Dyslipidaemia	
Smoking	
Family History of CVD	
Obesity (raised BMI/waist circumference)	

Table 4. Patients not on recommended drug compared to documented drug intolerance

DRUG	Drug prescribed n (%)	Drug not prescribed n (%)	If not prescribed- is there documented drug- intolerance n (%)	
Statin				
Aspirin				
ACEI				

Table 5. Use of drugs by gender and diabetes duration

MEDICATION	GENDER		DIABETES DURATION	
	Male	Female	<8 years	>8 years
Statin				
Aspirin				
ACEI				

Table 6. Comparison of 3 CHCs

PARAMETER	HPCHC	MPCHC	RCHC
Sample size			
Demographic			
1. Age			
Prescribing habits			
1. ACEI/ARB			
2. ASA (if risk factor)			
3. Statin			
Risk factors			
1. IHD			
2. HTN			
3. smoking			
4. Obesity			
5. Dyslipidaemia			

3. Literature Review

Literature search strategy

The literature search was performed in 2013. The following search engines were used to find relevant journal articles: Google Scholar, PubMed and Science Direct. WHO reports were also accessed. The search terms used were: diabetes, cardiovascular disease, adherence to guidelines, diabetes and statin, diabetes and angiotensin converting enzyme inhibitor, diabetes and aspirin

Burden of disease

According to the Global status report on non-communicable diseases 2010, published by the WHO, most deaths worldwide are caused by non-communicable diseases (NCDs). Almost two thirds of global mortality occurring in 2008 were due to NCDs, mainly comprising cardiovascular diseases (CVDs), cancers, diabetes and chronic respiratory diseases. Of particular concern is that it is not only the developed countries which are affected, but that the burden of CVD is already far advanced in poorer countries. The poorer countries will experience a "double burden from communicable diseases, as well as a rising incidence of non-communicable diseases such as diabetes and heart disease. It will be critical for policy makers to consider interventions to reduce the risk for CVD, and the report notes that the appropriate management of diabetes is an important factor in the reducing risk for CVD. There is evidence to show that Type 2 diabetes (T2DM) is a growing problem worldwide. Wild et al[2] examined epidemiological data to find global prevalence estimates for T2DM for the year 2000 and modelled projections for 2030. They predict that the number of people with diabetes would double. Sub-Saharan Africa, along with other developing regions, is expected to have the greatest increases in the number of people with diabetes. These findings indicate that diabetes will become an epidemic of global proportions, in both developed and developing countries.

The magnitude of the problem that Africa faces is significant, with studies showing that the prevalence of T2DM has increased considerably in Sub-Saharan Africa. This was highlighted in a systematic review looking at papers published on diabetes in Sub-Saharan Africa between 1999 and 2011, that investigated the prevalence, complications, mortality and economic burden of T2DM.[3] T2DM accounted for more than 90% of diabetes in Sub-Saharan Africa, [3] and the population prevalence of T2DM varied between countries, ranging from 1%

in rural parts of Uganda to 12% in urban Kenya. Studies investigating mortality from diabetes in Sub-Saharan Africa found high rates, with 5-year mortality rates ranging from 4%-57%.[3]

Bradshaw et al[4] investigated the burden of disease as a result of diabetes in South Africa in the year 2000. The estimated prevalence of diabetes in South Africans over the age of 30 years was 5.5%, and increased with age. In 2000, disease burdens attributable to diabetes were unacceptably high, with diabetes responsible for 4.3% of all deaths in South Africa. Diabetes was associated with 14% of IHD, 10% of stroke, 12% of hypertensive disease and 12% of kidney disease burden.

Studies conducted in the Western Cape confirm that T2DM is locally increasing in magnitude. A 1996 cross-sectional descriptive study in Mamre, a small working-class peri-urban settlement 55km from central Cape Town found the age-standardised prevalence of T2DM in the 30-65 years' age group to be 10.8%.[5] A later 2008 cross-sectional community-based study working-class urban Bellville South, Cape Town, found a high prevalence of T2DM (285) amongst adults over the age of 30 years. [6] This suggests a substantial increase in the prevalence of diabetes in a mixed-race working-class urban population, and indicate that diabetes is a growing important local public health problem.

Risk Factors for Type 2 diabetes

Risk factors for developing diabetes are increasing obesity levels, inactivity, ageing populations and urbanization with its associated lifestyle and dietary changes. [7] T2DM can remain undetected for many years, and is often only diagnosed after incidental blood or urine glucose testing. It has traditionally been defined by elevated blood glucose, and the management of diabetes in clinical settings is focussed on glucose control.[8]

T2DM is well known to be an independent risk factor for cardiovascular disease, and is an important cause of the decrease in life expectancy of affected people. Studies show that non-glycaemic factors are critically important in its management, and impact on associated cardiovascular risk and its effects. Lowering this risk involves using multiple approaches. Lifestyle modifications such as exercise, smoking cessation, dietary intervention and weight regulation are still vital aspects of diabetes management and prevention of CVD.[8]

Diabetes and Cardiovascular Risk

There is ample evidence showing that Type 2 diabetes is associated with a markedly increased CVD risk.[9,10] This has major public health repercussions, which will worsen with the projected increased incidence of diabetes. Fox et al[9] used subjects from the Framingham

Heart Study from a 50-year time period, and found that the proportion of CVD attributable to diabetes had increased over this time. They also found that, compared to other cardiovascular risk factors such as hypertension, smoking, hypercholesterolaemia and obesity, only diabetes showed an increase in the population attributable risk for CVD. In a five-year Danish study, Schramm et al [10] showed that diabetics had an increased risk for a myocardial infarction (MI), similar to that of non-diabetics with previous MI. They concluded that diabetics should be managed as if they have had prior CVD, and their cardiovascular risk factors should therefore be managed as aggressively as for nondiabetics with known CVD. These findings are supported by a Scottish study, where subjects were followed over 25 years, which showed that diabetics have a lifetime cardiovascular mortality risk similar to that of nondiabetics with CVD.[11]

A further prospective cohort study conducted among female nurses (who were free of known CVD) over a period of 20 years found that the risk of MI in subjects during a pre-diabetic period conferred a significantly higher risk of MI, as compared to the subjects who remained nondiabetic during the course of the study.[12]

The evidence points to both prediabetes and diabetes conferring a higher CVD risk profile, and the prognosis is even poorer once there is clinical CVD. Clinical care for diabetics should be directed at minimising this cardiovascular risk as much as possible, thus improving their chances of survival as well as their quality of life.

Guidelines for managing diabetes

Non-communicable diseases are reported to be increasing globally, and of major concern is that the number of diabetics is projected to double between 2000 and 2030.[2] Diabetes brings with it an elevated risk for cardiovascular disease. The Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) guidelines[13] developed guidelines to assist clinicians to better manage diabetes and prevent its complications. The guidelines are accepted nationally as evidence-based, and are applicable to the healthcare setting at a primary care level. These guidelines outline goals for the management of diabetes, and include factors like glycaemic control, lifestyle related risk factors and therapy for reducing cardiovascular risk and preventing cardiovascular events.

The guidelines recommend the following actions for reducing cardiovascular risk in Type 2 diabetics, and are outlined below, together with the evidence that they are based on.

Blood Pressure Treatment

The SEMDSA recommendation for blood pressure (BP) target in most patients with T2DM is ≤ 140/80 mmHg and ≥ 120/70 mmHg.[13] For diabetics with hypertension, an angiotensin-converting enzyme inhibitor (ACEI) should be the drug of choice as first-line therapy. Enalapril is the ACEI currently available in primary care services operated by MDHS. In cases of ACEI- intolerance, an angiotensin receptor blocker (ARB), Losartan, is available for prescription. Controlling the blood pressure has been shown in several trials to effectively reduce the associated cardiovascular morbidity and mortality. The HOPE study[14] showed that treating hypertensive diabetic subjects with the ACEI Ramipril was associated with a significant reduction in cardiovascular events. The ACEI effect was actually found to be independent of its effect on the blood pressure. The CAPPP (Captopril Prevention Project) trial used captopril to assess the effect on cardiovascular risk in diabetics with hypertension.[15] Compared with a diuretic and/or B-blocker regimen, captopril was shown to significantly reduce fatal and nonfatal cardiovascular events. Fatal cardiovascular events were reduced by half. Studies using perindopril-based regimens[16] also demonstrated cardiovascular protection for hypertensive diabetics.

These studies therefore support the utilisation of ACEI-based regimens in the management of hypertension in the diabetic patient, in the drive to reduce cardiovascular risk.

Statin Treatment

A statin should be prescribed for all Type 2 diabetics, regardless of baseline lipid levels: as primary prevention for those over 40 years with CVD risk factors, or secondary prevention if established CVD. Simvastatin is used in our setting, and can be initiated by a primary care doctor.

The evidence for local regimens comes from the Heart Protection Study[17] which compared simvastatin 40mg daily with placebo in randomly allocated diabetic subjects, and other individuals at high risk of vascular events. There was on average a 1.0mmol/L reduction of LDL-cholesterol levels in the simvastatin group, over the 5-year study period. The subjects allocated to the simvastatin group experienced about a 25% reduction in a first major vascular event. Cardiovascular risk reduction occurred both in the presence and absence of established coronary artery disease. There were also significant reductions in subsequent vascular events. These beneficial effects were found, regardless of the subjects' baseline lipid levels. The authors recommend that all diabetics who are at sufficiently high risk of vascular events should be considered for statin treatment, regardless of baseline lipid levels. The LIPID trial[18]

showed that pravastatin produced beneficial effects on cardiovascular risk, as the risk of a cardiovascular event was significantly reduced. The American Diabetes Association recommends that all diabetic patients should receive statin therapy: as secondary prevention for those with established CVD, and as primary prevention for those diabetics without known CVD, but over the age of 40 years and with one or more CVD risk factor. [19]

Statins have therefore been shown to be instrumental in the drive to reduce cardiovascular risk in diabetic patients, and their use in these patients is recommended by authorities on the subject.

Antiplatelet Agents

Aspirin (150mg/day) should be prescribed for all Type 2 diabetics: as primary prevention for those over 40 years or have CVD risk factors, or as secondary prevention for those with known CVD. The rationale for this is that acute ischaemic coronary events are mainly precipitated by thrombosis, [20] and this is the mechanism of CVD in diabetics. Antiplatelet agents such as aspirin have been shown to be a key element of thrombosis prevention in individuals at high risk of thrombotic events. This was confirmed in meta-analyses performed by the Antithrombotic Trialists Collaboration, [21] where aspirin use was associated with a reduction in serious vascular events.

The SEMDSA guidelines[13] recommend that aspirin treatment should be provided for those diabetics with a history of prior CVD, or those with increased cardiovascular risk. This includes diabetics over the age of 40, and those with additional risk factors, e.g. hypertension, smoking, dyslipidaemia and a family history of CVD.

Setting

Primary care plays a key role in the prevention and management of cardiovascular disease in high risk patients such as diabetics. Most diabetics are managed at a primary care level in the public healthcare system, and the Metro District Health Services (MDHS) oversees primary healthcare services in the Cape Town area through a network of CHCs. They serve mainly the uninsured, but also attend to patients on various medical aid schemes and funds. Patients are attended to by doctors and clinical nurse practitioners (CNPs), and attend monthly to receive their medication. The frequency of doctor/CNP visits will depend on how well the condition is controlled. Follow-up visits for chronic conditions like diabetes are usually 3-6 monthly. Diabetics who are poorly controlled are referred to specialist clinics at district or tertiary level hospitals.

Generally, the CHCs have been perceived to deliver a substandard level of care for chronic illnesses.

A 1999 study that reviewed diabetic and hypertensive control at primary care services in Cape Town[22] showed that, despite the prior dissemination of disease management guidelines at CHCs, there was still ongoing poor control of chronic diseases at primary care level. The study revealed suboptimal levels of hypertension and diabetes control. Two thirds of patients had uncontrolled blood pressure and more than half of diabetics had raised glucose levels. There was poor control of risk factors, with most patients having hypercholesterolaemia and high levels of smoking. Record keeping was also poor, with documentation of prescribing decisions frequently absent.

A study performed almost ten years later,[23] looking at the management of hypertension at CHCs in Cape Town, showed that deficiencies in the quality of care of chronic conditions at primary care level persisted. Poor adherence to clinical guidelines by clinicians was identified as one of the factors leading to poor blood pressure (BP) control.

Reviews of chronic disease control has been incorporated into regular audits as part of clinical governance functions driven by family physicians in Cape Town.[24,25] A 2008 audit, conducted at 15 CHCs within the Metro District Health Services (MDHS) addressed quality of care. [24] It included T2DM and reviewed the compliance of diabetic management with SEMDSA guidelines. These nationally accepted guidelines[13] for the management of T2DM are distributed to clinical staff at CHCs within the MDHS, and recommends an annual review of tests and examinations such as visual acuity and dilated eye exam, foot exam, creatinine and lipid profile. Others should be performed more frequently (quarterly- HBA1C, or twice yearly if stable). Important shortcomings were identified in areas such as clinical management, organization and continuity of care.

This inadequacy in the clinical management of diabetes is not limited to our setting. A study amongst family practitioners in Ontario, Canada, that compared family physicians' performance in managing T2DM to their recommended clinical guidelines found suboptimal levels of clinical care for diabetics with poor adherence to clinical guidelines.[25]

A Cape Town clinical audit, published in 2012, investigated whether previous audits (performed in 2005, 2007, 2008 and 2009) resulted in statistically significant improvements in diabetes management at CHCs.[26] The study findings revealed an improved performance in most clinical processes in diabetes management. The application of clinical audits was found

to have resulted in quality improvement in the management of diabetes in these resource-limited settings.

Adherence to guidelines

Several studies have been performed to investigate adherence to clinical guidelines for the prevention of CVD in diabetics. [27-29] The availability of guidelines does not necessarily lead to their application, and levels of adherence vary widely, ranging from about 20% in an Italian study, [27] to about 90% in a Scottish study.[28]

A Canadian study investigated management of cardiovascular risk factors and levels of adherence to Canadian Diabetes Association clinical guidelines for diabetics attending primary care centres.[29] The study found that a significant number of patients were not managed to Canadian guideline standards. About half had sub-optimal glycaemic control, and half did not achieve the target blood pressure. Many patients were also not receiving appropriate medical therapy to lower cardiovascular risk.

The introduction of evidence-based clinical guidelines to change prescribing habits has been shown to reduce healthcare costs. [30] Evidence-based clinical guidelines, however, should form the basis for the provision of good medical care, and prescribing habits of clinicians directly impact on the cost of healthcare. In an environment with limited resources such as in South Africa, cost should be factored into prescribing habits, to limit morbidity and mortality due to cardio-vascular complications of poorly controlled diabetes.

It is not known what the adherence to guidelines for the prevention and management of these diabetic complications at primary care level are. The study informed by this review is designed to ascertain this.

Motivation for this study

Many of the cardiovascular complications of T2DM are preventable. In view of the increasing magnitude of the T2DM burden, and the morbidity, mortality it causes, and the cost and demand for care arising from complications, it is important to ascertain whether proven preventive measures are being implemented. A study to determine the implementation of guidelines to manage cardiovascular risk factors at primary care level in Cape Town will add to our attempts to fight a disease which is threatening to reach epidemic proportions.

The level of adherence to recommended clinical guidelines impacts on quality and cost of care. So too can the extent to which they are made available at the facilities. Feedback can be provided to clinicians and management regarding the findings of the study.

(Words: 2707)

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4. Journal Manuscript

Cover Letter

The Editor

South African Family Practice

Dear Editor,

Attached please find a manuscript reporting on recent research conducted in primary care facilities. The article is titled: “Evaluating adherence to recommended clinical guidelines for the prevention of cardiovascular disease in patients with Type 2 diabetes mellitus at primary care level.”

From the literature this is an under-researched but important issue. It is hoped that the results of this study will help clinicians to see the importance of controlling cardiovascular risk factors, keeping good documentation and the value of evidence based clinical guidelines, all essential factors in good clinical care.

Yours sincerely,

Dr William Langenhoven.

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Abstract (word: 249)

Background

Globally, type 2 diabetes (T2D) is a significant cause of avoidable mortality and morbidity. It is a major risk factor for cardiovascular disease (CVD). Evidence-based guidelines lower cardiovascular risk in diabetics. Adherence to clinical guidelines for the prevention of CVD in South African primary care public sector facilities is unknown.

Aim

This study determined adherence of Cape Town primary care clinicians to recommended clinical guidelines for the prevention of cardiovascular disease in T2D.

Methods

This 2013 cross-sectional study extracted data from 300 folders of known T2D patients sampled from three Community Health Centres (CHCs). Compliance with guidelines, and patient demographic factors were analysed.

Results

Most (71% or 194/273) hypertensive diabetics were appropriately managed with first-line-medication - an Angiotensin Converting Enzyme Inhibitor (ACEI). There was appropriate supporting documentation for only 39% not on first line therapy. A fifth (22%) with drug intolerance received the recommended alternative. Most were appropriately prescribed a statin (74%) and aspirin (69%). Other cardiovascular risk factors were poorly controlled: mean weights were in the obese range (BMI=31.3 [SD: 5.7]); the mean total cholesterol level was 5.5 (SD: 1.4); there was incomplete data for smoking (19% had no record) and 93% had no record of a family history of CVD.

Conclusions

Whilst pharmacological interventions for the prevention of CVD were moderately implemented, patient factors – such as obesity and smoking were poorly addressed. Improving documentation, adherence to recommended clinical guidelines and, health promotion to address modifiable risks are required to improve quality of care for T2D.

Keywords: diabetes, cardiovascular risk, adherence, guidelines, Angiotensin Converting Enzyme Inhibitor (ACEI), statin, aspirin, Angiotensin Receptor Blocker (ARB)

Article

(Words: 3045)

Introduction

According to the World Health Organization (WHO), the biggest killers globally are non-communicable diseases, with more than half of all deaths linked to cardiovascular disease CVD).[1] Cardiovascular disease, important in the developed world, is a growing burden in poorer countries. In addition to the high burden of infectious disease epidemics and trauma, chronic diseases are increasingly a concern to health services and clinicians in developing countries.

A systematic review focussing on articles on diabetes in Sub-Saharan Africa published between 1999 and 2011, found that diabetes exerts a significant health burden in the region.[2] T2DM accounted for more than 90% of diabetes. The International Diabetes Federation (IDF) estimates that between 2011 and 2030 the number of people living with diabetes in Africa is expected to double to around 24 million.[3] South Africa is not spared from the diabetes epidemic, and local studies have shown a high prevalence of diabetes in many communities. A cross-sectional study conducted in Bellville South in urban Cape Town, found a high prevalence (28%, 95% CI: 22.0-30.3) of T2DM amongst adults over 30 years of age.[4]

Type 2 diabetes (T2DM) is an independent risk factor for CVD, and conversely CVD is an important cause for the decrease in life expectancy of people with diabetes. This has major public health repercussions, which will worsen with the projected increased incidence of diabetes. Fox et al[5] reviewing data from the Framingham Heart Study from a 50-year time period, found that the proportion of CVD attributable to diabetes had increased over this time. They also found that, compared to other cardiovascular risk factors such as hypertension, smoking, hypercholesterolaemia and obesity, only diabetes showed an increase in the population attributable risk for CVD. In addition, diabetics have greater morbidity and mortalities due to CVD compared to non-diabetic individuals.

Other research has found that diabetics have the same high risk of myocardial infarction (MI) as non-diabetics with a prior MI.[6] This suggests that diabetics should be managed as if they had prior CVD, and that their cardiovascular risk factors should be managed as aggressively as non-diabetics with known CVD.

Globally, the introduction of, and adherence to evidence-based clinical guidelines to change prescribing habits have been shown to reduce healthcare costs.[7] Evidence-based clinical guidelines should therefore form the basis for providing good medical care. However, in practice, obstacles are the approval of guidelines, their dissemination, and implementation by clinicians. Internationally, studies reviewing adherence to clinical guidelines for the prevention of CVD in diabetics in primary care public settings have found wide ranging levels of adherence: from 20% in an Italian study, [8] to 90% in a Scottish study.[9]

In South Africa, The Society for Endocrinology, Metabolism and Diabetes of South Africa[10] (SEMDSA) provides freely available, accepted clinical guidelines for the management of T2DM. They are based on consensus, and involved South African experts on diabetes and representatives from stakeholders including the Department of Health, and were formulated to be relevant to primary care.[10] They recommend that, based on their increased cardiovascular risk, type 2 diabetics should receive certain medications: 1) All diabetics should receive a statin, regardless of their cholesterol level, 2) Hypertensive diabetics should receive an angiotensin converting enzyme inhibitor (ACEI) as first-line anti-hypertensive therapy and 3) Low dose aspirin should be prescribed for diabetics as primary prevention for those with known IHD, and as secondary prevention for those with additional cardiovascular risk factors. These guidelines, although being best practice, were however, not officially released for use in the public sector.

Primary care plays an important role in the prevention of cardiovascular disease in high risk patients such as diabetics. Most diabetics in South Africa are managed through public sector health services, and in Cape Town these are administered by the Metro District Health Services (MDHS) through community health centres (CHCs). Patients are attended to by doctors and clinical nurse practitioners (CNPs).

Generally, the CHCs have been perceived to deliver a substandard level of care for chronic illnesses. A 1999 study that reviewed diabetic and hypertensive control at primary care services in Cape Town[11] showed that, despite the prior dissemination of disease management guidelines at CHCs, there was still ongoing poor control of chronic diseases at primary care level. The study revealed suboptimal levels of hypertension and diabetes control. Two thirds of patients had uncontrolled blood pressure and more than half of diabetics had raised glucose levels. There was poor control of risk factors, with most patients having hypercholesterolaemia and high levels of smoking. Record keeping was also poor, with documentation of prescribing decisions frequently absent. A study performed almost ten years later,[12] looking at the management of hypertension at CHCs in Cape

Town, showed that deficiencies in the quality of care of chronic conditions at primary care level persisted. Poor adherence to clinical guidelines by clinicians was identified as one of the factors leading to poor blood pressure (BP) control.

A 2008 audit, based on the SEMDSA guidelines, reviewed quality of care at 15 MDHS CHCs,[13] found significant shortcomings in the level of care provided. Among the findings were that patients were poorly controlled, staff lacked skills in screening for diabetes complications, and staff struggled with the workload. The causes were multifactorial, and recommendations included a structured and systematic approach to care.

A subsequent Cape Town clinical audit, published in 2012, investigated whether previous audits (performed in 2005, 2007, 2008 and 2009) resulted in statistically significant improvements in diabetes management at CHCs.[14] The study findings revealed an improved performance in most clinical processes in diabetes management. The application of clinical audits was found to have resulted in quality improvement in the management of diabetes in these resource-limited settings.

Aims and Objectives

This study aimed to determine adherence of Cape Town primary care clinicians to recommended clinical guidelines for the prevention of cardiovascular disease in type 2 diabetics.

The objectives were firstly to determine the demographic characteristics and risk profile for CVD of type 2 diabetic patients attending the CHC, and secondly to determine the proportions of diabetic patients at a primary care level who were being treated according to recommended guidelines to reduce cardiovascular risk: lipid treatment – prescription of a statin for all diabetics; appropriate blood pressure treatment – ACEI as first line treatment in the hypertensive diabetic or the accepted alternative if contraindications existed; antithrombotic treatment – secondary prevention for diabetics with a history of CVD, or as primary prevention in those with risk factors. CHCs were also compared regarding level of adherence to the guidelines. This would show if there was any significant difference in prescribing practices between the CHCs.

Methods

This cross-sectional study was performed in 2013 and all data collection was performed by the author. One hundred folders from each of the three facilities were sampled to power the study with a 95% confidence level and precision of 10% for an unknown proportion of adherence overall. Systematic sampling of all T2DM folders of patients fulfilling the eligibility criteria was conducted. Reception staff collected folders of patients who are known to attend the diabetes "club" on 3 separate days, and every third folder was chosen, and marked. Inclusion criteria were: type 2 diabetics of age 40 years or older, being a documented chronic disease clinic attendee with at least three visits during the previous year for diabetes, signalling a person with established disease in care.

Data from the clinical notes, as well as the structured clinical record (SCR), [14] a standard tool used for all "chronic" or "club" patients, were captured. The SCR contains information about patients' demographic data and cardiovascular risk factors: hypertension, history of IHD (ischaemic heart disease), smoking, family history of IHD, BMI (body mass index) and total cholesterol level). Measurements, such as blood pressure and blood sugar, from each chronic visit are recorded on this sheet. Clinical information, medication and medical history, e.g. cardiovascular risk factors were obtained from the clinician notes in the folder.

Adherence to SEMDSA guidelines was measured by the appropriate use of an ACEI in hypertensives, lipid-lowering medication for all diabetics, and aspirin for those diabetics with risk factors. In cases where adherence was not met, evidence of the prescriber providing a justification was searched for by folder review. If a reason was documented, then the non-adherence was classified as "justified non-adherence". Not all criteria were relevant for all patients: some diabetics were not hypertensive, and were not included in the ACEI calculation; patients not on aspirin, with no cardiovascular risk factors, were categorized as "not applicable". Data regarding prior intolerance to specific drugs was also extracted.

Ethics approval (HREC REF 191/2013) for the study was obtained from the UCT Health Research Ethics Committee. Permission to conduct the study at the facilities was obtained from the MDHS and the relevant facility managers, and no personal identifiers were recorded.

Data analysis

Data were entered into an Excel spreadsheet. Statistical analysis was performed using the statistical software, SAS. Data analysis was descriptive, and results are presented as frequencies and percentages for categorical variables, and mean and standard deviation (SD) for continuous variables. Fisher's exact test, ANOVA or chi-square tests were used where appropriate to compare the CHCs. Results were considered significant at $p<0.05$.

Results

Three hundred patient folders, 100 from each of three facilities were reviewed. Data pertaining to demographic variables was missing in folders from all three facilities. Patient demographic details are given in Table 1. Overall, the mean age of patients was 60.4 ± 11.2 years, and most (71.7%) were female. From clinical notes, the vast majority – 91% – were classified as hypertensive. For many, cardiovascular risk factors were poorly controlled, with mean BMI's in the obese range (31.3 [SD 5.7] kg/m^2, n=200) and the mean total cholesterol was 5.5 mmol/l (SD 1.4). As is shown in Table 1, data was incomplete in folders for several cardiovascular risk factors, such as BMI, smoking status, family history of CVD, total serum cholesterol and existing IHD.

Patient data was compared by health centre to determine if there were differences by patient demographic or disease profile. The three facilities had equivalent proportions of patients by age, gender, smoking, hypertensive status and dyslipidaemia. Significant differences by facility, however, existed for known IHD, family history of CVD, and BMI ($p<0.05$). CHC1 only had 6 patients documented with a history of IHD, whereas CHC2 and CHC3 had 15 and 21 respectively. Information about family histories of IHD was largely absent, with CHC3 faring best with 20% compared to one each for the other two CHCs. BMI recording was poor for all three CHCs, with 101 patients having no documented BMI calculation. The difference in documentation between the three CHCs was significant, and only half of folders reviewed at CHC3 had a recorded BMI. The mean BMI at CHC2 was 29.5 (overweight), while the mean BMI's at the other two CHCs fell in the obese category (>30) ($p=0.0012$).

Table 1. Patient Demographics and risk factors for complications of T2DM

Characteristic	All Patients (n=300)	Community Health Centre			p-value
		CHC 1 (n=100)	CHC 2 (n=100)	CHC 3 (n=100)	
Age (years), Mean (SD)	60.4 (11.2)	59.7 (12.1)	60.8 (10.7)	60.6 (10.9)	p=0.7733
Gender					
Female (%)	215 (71.7%)	75 (75%)	69 (69%)	71 (71%)	p=0.6675
Hypertension	273 (91%)	88 (88%)	93 (93%)	92 (92%)	p=0.4254
Known IHD	42 (14%)*	6 (6%)	15 (15%)	21 (21%)	p=0.0062
Smoker	74/243**	26/76	24/85	24/82	p=0.4931
Family history of CVD	19/22***	1/1	1/1	17/20	p<0.0001
BMI					
n	199^	88	62	49	
Mean (SD)	31.3 (5.7)	31.3 (4.9)	29.5 (5.4)	33.4 (6.7)	p=0.0012
Dyslipidaemia					
n	274^^	94	87	93	
Total cholesterol (mmol/l), SD	5.5 (1.4)	5.6 (1.5)	5.6 (1.4)	5.2 (1.3)	p=0.1708

*258 patients there was no indication of the IHD status.

**57 patients there was no indication of smoking status.

***278 patients this data was absent.

^101 patients there was no recorded BMI.

^^26 patients had no total cholesterol result in the folder.

Adherence to guidelines

Table 2 shows the levels of adherence to the SEMDSA guidelines overall. The results for the individual CHCs are shown and compared to each other. Appropriate prescription of antihypertensive medication overall was 201 (73.6%). This figure includes the 194 (71.1%) with appropriate prescription of an ACEI as well as those 7 patients who had ACEI-intolerance who were prescribed an ARB. Of the seventy-nine hypertensive patients who were not prescribed an ACEI, only 31 (39.2%) had a documented reason for not getting an ACEI. For the 31 patients with intolerance to the drug, only 7 (22.6%) received the recommended alternative, i.e. an ARB. Four (of the 24 who did not receive an ARB) patients were reported to have an ACEI allergy.

Adherence to the use of a statin was 74.3% overall. None of the 77 patients who were not receiving a statin had a documented reason for this. Adherence to the prescription of aspirin in those with increased cardiovascular risk was 69.3%. For the 92 patients not receiving aspirin, 18 (19.6%) did not require it, and only 13 (14.1%) had a documented reason for its absence.

There was no significant difference between the CHCs for prescription of ACEI for hypertensives, and use of aspirin in patients with risk factors. There was also no difference between clinics in patient profiles precluding aspirin prescription (p=0.3208). There were however differences between the CHCs for the proportion of patients not requiring aspirin . CHC1 had 18 patients with no documented risk factors for CVD, and hence did not require aspirin, while both the other CHCs had none. Prescription of statins differed between facilities and ranged from 84% (CHC1) to 68% (CHC2) (p<0.05).

Table 2. Adherence to SEMDSA guidelines

Characteristic	All Patients (n=273)	95% CI	Community Health Centre			p-value
			CHC 1 (n=88)	CHC 2 (n=93)	CHC 3 (n=92)	
1. ACEI						
Use of ACEI in HTN	194 (71.1%)	64.6 -77.4	59 (67%)	62 (66.7%)	73 (79.3%)	p=0.0985
Justified non-adherence	31 (39.2%)		11 (38%)	12 (38.7%)	8 (42.1%)	p=0.9560
ACEI-intolerance (n=31) +ARB prescribed	7 (22.6%)		2 (18.2%)	3 (25%)	2 (25%)	P=0.5285
ACEI/ARB allergy			0 (0%)	2 (16.7%)	2 (25%)	
2. Statin						
Use of statin in primary prevention	223 (74.3%)	68.2-79.8	84 (84%)	68 (68%)	71 (71%)	p=0.0200
Justified non-adherence	0/77		0	0	0	
3. Aspirin						
Use of aspirin if risk factors	208 (69.3%)	62.7-75.0	70 (70%)	69 (69%)	69 (69%)	p=1.000
Justified non-adherence	13 (14.1%)		3 (10%)	7 (22.6%)	3 (9.7%)	p=0.3208
Not applicable (no risk)	18		18 (60%)	0 (0%)	0 (0%)	p<0.0001

Discussion

Diabetes accounts for a significant health and economic burden locally and worldwide, and the predictions are that the global prevalence of diabetes will increase.[1-4] Research has shown T2DM to be an important contributing risk factor for CVD,[5] and CVD is as a leading cause of mortality in diabetic patients. [6] The management of diabetes must therefore cover not only blood sugar control, but also address the reduction of risk factors for cardiovascular disease.

The SEMDSA has published guidelines for the management of T2DM.[10] These guidelines provide recommendations for blood pressure and lipid treatment, and for the use of aspirin. The guidelines are freely available, but it is not known how widely they are disseminated to facilities managing diabetics, or if their

implementation by clinicians is monitored. Studies performed elsewhere[8,9] have reported varying levels of adherence to guidelines. This study aimed to determine if type 2 diabetic patients attending primary care clinics were prescribed treatment, as recommended by SEMDSA guidelines, to reduce their cardiovascular risk.

This study revealed deficiencies in both adherences to disease management guidelines and documentation of individual patient management. Cardiovascular risk reduction was poor. The results showed obesity to be a major problem (mean BMI 31.3 ± 5). There were moderate levels of adherence to clinical guidelines, developed to reduce cardiovascular risk in diabetics. Appropriate use of ACEI in hypertension and use of statins was 71% and 74% respectively, with appropriate aspirin use at 69% overall.

Reasons for observed differences between facilities in prescribing patterns, such as statins, are unknown and require further investigation. It may be due to clinician ignorance about latest guidelines for diabetic management. Continued medical education may be unevenly implemented at the various facilities, and this merits attention.

In-service updates about the latest evidence-based clinical guidelines should promote the use of guidelines amongst clinicians, and needs to be scheduled into the working routine in the services. In this study updates and training would have increased clinicians' knowledge about the importance of identifying cardiovascular risk factors in diabetic patients and its appropriate management. A study at a South African district hospital's diabetic clinic showed that the quality of care, as well as diabetic control, improved after the introduction of a physician education programme. [15]

Documentation across all facilities was poor for both the structured clinical record (the chronic patient form to record investigations and cardiovascular risk) and the clinical notes which contain prescribing decisions. The results obtained from this study compared well with international studies reviewing clinician adherence to therapeutic guidelines for diabetic patients. In different settings levels of adherence varied widely, ranging from 20% in an Italian study,[8] to 90% in a Scottish study.[9] Nonetheless, they also show that in our setting there is still room for improvement.

Limitations

This study audited one aspect of assessing adherence to clinical guidelines, i.e. pharmacological therapy. It did not explore the facilitators or barriers to good adherence. These factors may include clinicians' inadequate knowledge of appropriate therapy; high turnovers of medical staff at the CHCs; inadequate orientation of new clinical staff to expected practice; poor availability of clinical guidelines; and the presence/absence of regular in-service education session. In addition, the presence of health promotion messaging in clinical notes, in the facility and dedicated health promotion staff was not collected.

Poor or insufficient documentation contributed to a potential misclassification bias as the researcher classified absent information as non-adherence to guidelines, and this would result in an underestimation of performance. The facility differences observed may be the result of the different clinician categories prescribing practices - doctors or CNPs. The study was not powered to compare different categories of clinicians, i.e. doctors vs clinical nurse practitioners. It is difficult to identify the clinician category from clinical notes and this would have affected the sampling strategy.

Conclusion and recommendations

The study points to areas for improvement in the management of diabetes at primary care level. Prevention of cardiovascular disease and risk factor reduction should be an important goal in the management of the diabetic patient, but cardiovascular risk factors were found to be poorly controlled. Higher levels of adherence to recommended clinical guidelines by clinicians are essential for improving quality of care. This can be aided by the facilities improving awareness and availability of these guidelines. Good clinical notes, which includes documenting the rationale for prescribing decisions, improves continuity and quality of care. This would contribute to reducing costs arising from the consequences of inadequate management.

Continued medical education at the CHCs would help to keep clinicians informed of current evidence-based guidelines, and increase the rates of guideline implementation. Processes, such as audit cycles, with feedback to clinicians, would be helpful to monitor and identify areas for improvement in primary care prescribing. In addition, a stronger focus on non-pharmacological health promotion messaging around obesity is critical.

Consideration of the use of other metrics for obesity that are stronger predictors of cardio-vascular risk such as waist circumference (WC) [16] are needed. While BMI is an important predictor of health risk, WC predicts both abdominal and non-abdominal fat. This is currently not included in the SEMDSA. BMI is widely used in

primary settings as a tool to measure for obesity, yet WC is simpler to measure. This suggests that it would be more appropriate for the CHCs to replace BMI with WC on the structured clinical record.

A revised primary care oriented guideline with useful tools for in-service training that uses a bio-psycho-social approach, if implemented, would assist improving the care of T2D. This guideline would incorporate a focus on both clinical skills, management guidelines, including appropriate health promotion messages. The tools should include revised stationery, e.g. a modified structured clinical record which includes SEMDSA medication guidelines, that is easy to use and store, and material that facilitate health promotion in busy primary care services.

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5. Appendices

Ethics approval letter

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Human Research Ethics Committee
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Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: lamees.emjedi@uct.ac.za
Website address: http://www.health.uct.ac.za/research/humanethics/forms/

18 April 2013

HREC REF: 191/2013

Dr W Langenhoven
C/o Dr V Zweigenthal
Public Health & Family Medicine
Falmouth Building
Medical School

Dear Dr Langenhoven

PROJECT TITLE: EVALUATING ADHERENCE TO RECOMMENDED CLINICAL GUIDELINES FOR THE PREVENTION OF CARDIOVASCULAR DISEASE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AT PRIMARY CARE LEVEL

Thank you for your letter to the Faculty of Health Sciences Human Research Ethics Committee dated 12 April 2013.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted until 28 April 2014.

Please submit to the HREC a Progress Report Form if the study continues beyond the approval period. Please submit a Closure Report Form on completion of the study. (Forms can be found on our website: http://www.health.uct.ac.za/research/humanethics/forms/

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR MARC BLOCKMAN
CHAIRPERSON, FHS human research ethics committee

Federal Wide Assurance Number: FWA00001637.

Lemjedi

Acknowledgements

I would like to thank my supervisor Virginia Zweigenthal, for her extreme patience, guidance and advice during the process of developing this research.

Thank you to the records staff at Hanover Park, Mitchells Plain and Retreat Community Health Centres for supplying me with the necessary folders to work through.

Thank you to my family for your support.

Data collection sheet

Name of CHC	Patient folder no.	Age	Sex	Known T2DM	3 visits in last year	HTN	IHD	ACEI prescribed	ACEI non-prescription justified	Statin prescribed	Statin non-prescription justified	ASA prescribed (if risk factor for CVD)	ASA prescribed without risk factor for CVD	ASA non-prescription justified
1														
2														
3														
4														
5														
6														
7														
8														
9														

Data capture sheet continued:

Name of CHC	Obesity	Dyslipidaemia	Family history of CVD	Smoker					
1									
2									
3									
4									
5									
6									
7									

Patient Demographics and risk factors for complications of T2DM

Characteristic	All Patients (n=300)	Community Health Centre			p-value
		CHC 1 (n=100)	CHC 2 (n=100)	CHC 3 (n=100)	
Age					
Gender					
Female (%)					
Hypertension					
Known IHD					
Smoker					
Family history of CVD					
BMI					
n					
Mean (SD)					
Dyslipidaemia					
n					
Total cholesterol (mmol/l)					

Adherence to SEMDSA guidelines

Characteristic	All Patients	95% CI	Community Health Centre			p-value
			CHC 1	CHC 2	CHC 3	
1. ACEI						
Use of ACEI in HTN						
Justified non-adherence						
ACEI-intolerance +ARB prescribed						
ACEI/ARB allergy						
2. Statin						
Use of statin in primary prevention						
Justified non-adherence						
3. Aspirin						
Use of aspirin if risk factors						
Justified non-adherence						
Not applicable (no risk)						

Journal submission guidelines

Instructions for authors for publication-ready format were taken from:

South African Family Practice Journal, Submissions, Author guidelines. Available from http://www.safpj.co.za/index.php/safpj/about/submissions#authorGuidelines.
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The following are sample references:

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