Diabetic status of patients presenting for dental treatment

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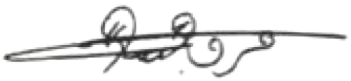
Declaration

I declare that (Diabetic status of patients presenting for dental treatment) is my own work and has not been previously submitted for any degree to any other university. All the sources used or quoted have been acknowledged.



Dedication

To my mother, my husband and all my family and friends for their constant encouragement, support and love

Acknowledgement

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- Dr. H Holmes: for her supervision and guidance through the steps of this project.
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Definitions

Diabetes Mellitus (DM) is a chronic metabolic disorder of carbohydrate, protein and fat, due to deficiency or diminished effectiveness of insulin and characterized by hyperglycemia, glycosuria and subsequent complications of microangiopathic and macroangiopathic changes (ADA, 2014).

Type 1 diabetes, was also called insulin-dependent IDDM, it is believed to be an autoimmune condition. It is more common in juveniles, and often starts in childhood. It accounts for between 5-10% of all diabetics and results from the body's failure to produce enough insulin (insulin deficiency) (Kharroubi et al. 2015) (DAD, 2010).

Type 2 diabetes, was referred to as Non-insulin dependent (NIDDM), is the most common type. It accounts for between 90-95% of all diabetic individuals and is more common in elder age. NIDDM develops due to the failure of cells to respond to insulin properly (insulin resistance) (Kharroubi et al. 2015) (DAD, 2010).

Hyperglycemia (high blood sugar) is a condition in which an excessive amount of glucose circulates in the blood plasma and the blood sugar level raise above 11.1 mmol/L (200 mg/dL). However, the symptoms may not be noticeable until the blood glucose level is higher than 15 - 20 mmol/L (250 - 300 mg/dL). A subject with a constant range between 5.6 - 7mmol/L (100 - 126 mg/dL) (ADA guidelines) is considered hyperglycemic, while more than 7 mmol/L (126 mg/dL) is generally considered to have diabetes. Chronic levels exceeding 7 mmol/L (125 mg/dL) can produce organ damage (Vandijck, D.M., 2008).

Prediabetes (intermediate hyperglycemia) defined as the blood sugar level is higher than normal but not high enough to be diabetes. The glycemic variables those are higher

than normal, but lower than diabetes thresholds, is a risk state that defines a high chance of developing diabetes. Without lifestyle changes, people with prediabetes are very likely to progress to type 2 diabetes (Tabák et al. 2012).

Fasting blood glucose (FBG) is a blood test used to measure the level of glucose in the blood after at least an eight-hour fast. Therefore it is not affected by recent food intake (ADA, 2013). The terms FBG and Fasting Plasma Glucose (FPG) are used interchangeably.

Random blood glucose (RBG) is an amount of glucose dissolved in circulating blood, recorded irrespective of when food was last ingested. It is also referred to as capillary blood glucose (CBG), which assumes a recent meal has been taken and thus has higher reference values than the fasting blood glucose test (ADA, 2103). The terms RBG and Random Plasma Glucose (RPG) are used interchangeably.

Abbreviations

DM	Diabetes Mellitus
UDM	Undiagnosed diabetes mellitus
IDDM	Insulin dependent diabetes mellitus
NIDDM	Non-insulin dependent diabetes mellitus
FBG	Fasting blood glucose
FPG	Fasting plasma glucose
RBG	Random blood glucose
RPG	Random plasma glucose
OGTT	Oral glucose tolerance test
HbA1C	Hemoglobin A1C test
ADA	American Diabetes Association
WHO	World Health Organization
ICU	Intensive care unit

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Abstract

Introduction: The prevalence of Diabetes mellitus (a non-communicable disease) is increasing worldwide. In 2008, it was declared one of the major non-communicable diseases in South Africa, affecting 4.6% of the population (cited in Pretorius, 2014). Of concern is the large number of people who are undiagnosed and thus present for treatment at a late stage of the disease. This has prompted the need for screening of patients as Diabetes Mellitus has serious immediate and long-term complications.

Aim: To assess the diabetic status of patients presenting for dental treatment at University of Western Cape (UWC) Maxillofacial outpatient clinic.

Objectives:

To assess the incidence of undiagnosed Diabetes Mellitus

To determine the prevalence of Diabetes Mellitus in patients presenting for dental treatment.

To describe intraoral soft tissue lesions observed in these patients.

Methodology

A cross-sectional observational study was carried out on 400 consecutive adult patients, 18 years or older, presenting for dental treatment at the UWC Maxillofacial department. Patients who were younger than 18 years of age, pregnant or were unable to open their mouth were excluded.

Method of blood collection

Random blood glucose levels (RBG) were measured using a point of care instrument (glucometer). Peripheral blood was collected by lancing the patient's fingertip; whereafter the blood droplet was placed onto a test strip and a value was obtained from the glucometer. The blood glucose level was measured in mmol/L.

Results:

Results of this study revealed that:

- Of the 400 patients included in the study,
  - The prevalence of diabetes was 10% (*n*= 40).
  - The incidence of diabetes was 1% (*n*=4).
  - Prediabetic patients accounted for 2.7% (*n*= 11).
- In total 51 (12.7%) out of 400 were either known diabetic patients or newly diagnosed (both prediabetic and diabetic) and 15 (29.4%) out of these 51 patients are unaware of their status (undiagnosed). Both prediabetic and diabetic patients were referred for confirmatory tests.
- 42.5% (*n*=17) of diabetic patients (*n*= 40) had soft tissue lesions, which was higher than in those patients with normal blood glucose levels 39.2% (*n*=137 out of 349). Diabetic patients with oral *candidiasis* accounted for 25% (*n*=10) compared to those with normal blood glucose levels 18.3% (*n*=64 out of 349).
- 45% (*n*=23) of hyperglycemic patients (*n*= 51) had soft tissue lesions and 23.5% (*n*=12) of those hyperglycemic patients had oral *candidiasis*, compared to those with normal blood glucose levels 18.3% (*n*=64 out of 349).

Conclusion:

The results of this study support the need for general screening of all patients to facilitate early diagnosis of this disease.

Key words: Diabetes Mellitus, incidence, prevalence, random blood glucose, soft tissue lesion

1- Background and purpose of the study

Diabetes Mellitus (DM) is the most prevalent endocrine disorder, affecting approximately 6% of the population worldwide (cited in Adeghate, et al. 2006). In 2010, the global disease prevalence amongst adults aged 20-79 years was 6.4% and is projected to be 7.7% by 2030. In developed countries between 2010 and 2030, the increase is anticipated to contribute approximately 20% and as high as 69% in developing countries (Shaw et al. 2010). Similarly, the prevalence of type 2 Diabetes Mellitus in children and adolescents is on the increase and appears to be related to obesity. Diabetes is becoming more common in younger people, placing an increasing demand on prevention and early diagnostic strategies; in order to reduce treatment of diabetic related complications (Reinehr, T., 2013).

Diabetes Mellitus has an asymptomatic, latent period during which the disease is not clinically detected and as a result a substantial proportion of people with diabetes remain undiagnosed (UDM) (Sosale et al. 2014). Diabetes can be referred to as a "silent killer" and if not diagnosed early, results in multisystemic complications, which can be acute and chronic. Acute complications include hyperglycemia, hypoglycemia and ketoacidosis. Chronic complications comprise retinopathy, neuropathy, nephropathy, cardiovascular complications, delayed wound healing (Huang et al. 2014) and fetal death, especially in poorly controlled pregnant diabetics (WHO, 2016).

In 2013, a study in Northern Africa reported the prevalence of a broad range of chronic diabetic related complications. They ranged from 8.1% - 41.5% for retinopathy, 6.7% - 46.3% for nephropathy, 21% - 22% for albuminuria and 21.9% - 60% for neuropathy (Bos, et al. 2013). This broad variation was related to the different geographical locations of the study population, which were done in different countries. High prevalence values were seen in urban regions, resource poor areas as well as in parts

where the majority of the population were uneducated and lacked facilities for specialist consultation. The role of ethnicity could not be determined, as it was not reported.

Chronic complications not only comprise the major cause of morbidity and mortality for diabetic individuals, but also is often their initial presenting symptoms, leading to their diabetic diagnosis (Sosale et al. 2014). Diabetic related complications might be prevented by early diagnosis, but once they have developed and the diabetes is left untreated, they will worsen progressively. This highlights the importance of screening for both micro and macro vascular complications along with assessment of cardiovascular risk factors in newly diagnosed type 2 diabetic patients. This early diagnosis could assist to prevent or stop the progression of the complications and negate the need for intensive management (Sosale et al. 2014).

Hyperglycemia is an abnormal high blood glucose level, in which an extreme amount of glucose circulates in the blood and the blood sugar level is elevated above 11.1 mmol/L (200 mg/dL). It is used to measure the disease control following an established diabetes diagnosis (Model, C.C., 2015). Symptoms of untreated/undiagnosed diabetes include polyuria, polydipsia, weight loss, mostly with polyphagia, and blurred vision. Impairment of growth and susceptibility to certain infections may be also associated with chronic hyperglycemia. Long-term complications of diabetes include retinopathy with potential loss of vision; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers, amputations, and Charcot joints (Neuropathic arthropathy); and autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction. Increased incidence of atherosclerotic cardiovascular, peripheral arterial, and cerebrovascular disease has been noticed in patients with diabetes. Hypertension and abnormalities of lipoprotein metabolism are often found in people with diabetes (ADA, 2014).

Chronic hyperglycemia commonly leads to severe complications, such as increased postoperative wound infections and worsening the prognosis in brain injuries and stroke patients (McCowen et al. 2001). Hyperglycemia in patients with DM who undergo

surgery is accompanied by higher rates of surgical site infection, myocardial infarction, stroke, and death even occurring in up to two thirds of surgical patients who are not diabetic. The higher rate of complications amongst non-diabetic patients may reveal a more extreme inflammatory and stress response that causes these patients to have the same level of hyperglycemia as patients who have DM.

Perioperative hyperglycemia may raise the risk of adverse effects more significantly in non diabetic patients (NDM) than in those with DM. Increased level of stress may be the reason for the increased rate of complications in non-diabetic patients, with hyperglycemia acting as a marker rather than a cause for the problem. The increased risk of complications in these patients may be the result of under diagnosis of diabetes that is revealed in the surgical setting (Kotagal et al. 2015).

There is an increased risk of complications associated with hyperglycemia in patients without history of diabetes when compared with diabetic patients. Insulin and its anti-inflammatory effects play a role to avoid acute hyperglycemia and its complications in these patients (Kwon et al. 2013). This supports the need to check the diabetic status of each patient before they undergo any surgery.

A diagnosis of DM is largely based on increased blood glucose measurements but varies according to the method employed. The fasting blood glucose (FBG) determines the blood sugar level in a fasting state (i.e. not having eaten for 8-12 hours) and must be conducted on 2 separate occasions. Diabetic status is conferred if blood glucose levels are >126 mg/dL (7.0 mml/L) on both occasions (ADA, 2013). The oral glucose tolerance test (OGTT) assesses the body's ability to utilize carbohydrates. A standard dose of glucose is consumed and the blood glucose is measured 2 hours thereafter (as described by World Health Organization). The random blood glucose (RBG) test can be performed at any time and does not require a specific period of fasting. A glucose value of ≥ 200 mg/dL (11.1mmol/L) along with symptoms of hyperglycemia indicates a diagnosis of diabetes (ADA, 2013).

HbA1C measures the glucose levels bound to hemoglobin, which has been in the blood over the past 3 months. It provides the ratio of glycosylated hemoglobin in relation to the total hemoglobin in circulation. Plasma glucose values of > 6.5% is indicative of diabetes. This test serves as an overall marker of the average glucose levels over a 2-3 month period (IEC, 2009).

	Prediabetes	**Diabetes**
HbA1c	5.7–6.4%	≥6.5%
FBG	100–125 mg/dL / (5.6–6.9 mmol/L)	≥126 mg/dL / (7.0 mmol/L)
OGTT	140–199 mg/dL / (7.8–11.0 mmol/L)	≥200 mg/dL / (11.1 mmol/L)
RBG	140 – 200 mg/dL/ (7.8 - 11.1mmol/L)	≥200 mg/dL / (11.1 mmol/L)

Table 1: Criteria for the Diagnosis of Prediabetes and Diabetes (ADA, 2013).

Diabetes is strongly associated with oral problems of which periodontal disease is the most significant (Stanko et al. 2014; Jha et al. 2014). Its role as a risk factor is well documented, showing a bi-directional relationship between periodontal disease severity and diabetic complications (Chapple et al. 2013; Mawardi et al. 2015). Other oral problems associated with DM include candidiasis, dental caries, tooth loss, gingivitis, lichen planus, neurosensory disorders (burning mouth syndrome), salivary dysfunction, xerostomia, and taste impairment (Leite et al. 2013). These oral complaints associated with diabetes may support the fact that non-hospital and medical facilities, such as dental clinics, are a good source for diabetic screening.

The rising prevalence of Type 2 Diabetes Mellitus, especially in the younger population, the delay in diagnosis and the morbidity associated with complications of undiagnosed diabetes emphasizes the need for screening, prevention and early diagnostic strategies. It is thus the purpose of this study to investigate the utility of random blood glucose collection as a screening tool to facilitate early referral and diagnosis of DM amongst outpatients attending the Maxillofacial Clinic at the UWC dental faculty. The term diabetic patient will be used for patients with a RBG value > 11.1 mmol/L or FBG value > 7.0 mmol/L.

2- Literature review:

2.1- Diabetes mellitus and risk factors

Diabetes mellitus, commonly referred to as diabetes, is a metabolic disorder caused by an absolute or relative deficiency of insulin. This can be due to low insulin production by the pancreatic beta cells, or insulin resistance in the peripheral tissues (Sousa et al., 2011). When insulin is lacking or its action is stopped, glucose cannot enter cells and causes loss of energy and weakness. In addition, glucose accumulates in the blood (hyperglycemia) and overflows into the urine (glycosuria) along with increased urine volume (polyuria).

The risk factors for developing diabetes are numerous. A family history of diabetes is considered a major risk factor, with an increased risk seen when a close relative such as a parent, is diabetic. Obesity also plays a role, possibly because of the presence of resistin, a circulating protein with no homology to any known hormone, cytokine, or other intercellular signaling molecule. It is secreted specifically by adipocytes and has actions that antagonize insulin action (Steppan et al.2001), which makes cells resistant to insulin (Pretorius, 2014). The age pattern of diabetes prevalence is expected to differ between African and higher income regions. The majority of diabetes in Africa is prevalent in working-age people, between the age of 40 and 60 years, rather than those older than 60 years (Shaw et al. 2010).

Ethnicity and race is known to affect the prevalence of diabetes in some countries, with Type 1 diabetes being more prevalent amongst Caucasians in European countries such as Sweden and Finland. Type 2, however, is more common amongst blacks, Asians and Hispanics (Pretorius, 2014). A 10-year follow-up study conducted by Motala, A.A., et al. in 2003, revealed a high incidence of Type 2 diabetes in a South African Indian population. The significant predictors for its development are a higher 2-h post-load

plasma glucose, body mass index and obesity at baseline. A sedentary lifestyle and diet plays an important role in increasing the prevalence and incidence of diabetes. Reduced physical activity due to urbanization may increase the chance of DM.

2.2- Classification of diabetes mellitus:

Type 1 diabetes, was formerly called insulin-dependent IDDM, appears to be an autoimmune condition. It is more common in juveniles, and often begins in childhood. It accounts for between 5-10% of all diabetics and results from the body's failure to produce enough insulin (insulin deficiency) (Kharroubi et al. 2015; DAD, 2010).

Type 2 diabetes, was formerly referred to as Non-insulin dependent (NIDDM), is the most common type. It accounts for between 90-95% of all diabetic persons and is more common in the elderly. NIDDM arises due to the failure of cells to respond to insulin properly (insulin resistance) (Kharroubi et al. 2015; DAD, 2010).

Type 3 Gestational diabetes, has its onset in the second or third trimester of pregnancy, usually in persons with no previous history of diabetes. It usually resolves after delivery (Kharroubi et al. 2015; DAD, 2010).

2.3- Diagnosis of Diabetes Miletus

Globally, the prevalence of diabetes is increasing and its complications are major contributors of morbidity and mortality. It may remain undetected for many years, gradually leading to severe complications and thereby incurring healthcare costs for management of these complications (Beagley et al. 2014).

A confirmed diagnosis of diabetes has been based on 2 methods of glucose measurement criteria, i.e. either the estimation of plasma glucose (such as FPG or the 75-g OGTT) or HbA1c (Kharroubi et al. 2015). There is no single assay measuring hyperglycemia that could be considered the gold standard for the diagnosis of diabetes. Moreover, a

measure that captures chronic glucose exposure is more likely to be more confirmatory in establishing a diagnosis of diabetes than a single measure of glucose (ADA, 2010).

Diabetes is diagnosed if the patient has a fasting plasma glucose level of ≥126 mg/dL (7.0 mmol/L) on two separate occasions, a plasma glucose ≥ 200mg/dL (11.1mmol/L) after 2-h OGTT, HbA1c ≥ 6.5% (48mmol/mol) or random plasma glucose ≥ 200 mg/dL (11.1mmol/L), along with symptoms of hyperglycemia (Kharroubi et al. 2015).

	Diabetes	**No of tests required**
FPG	≥126 mg/dL / (7.0 mmol/L)	Two separate occasions
OGTT	≥200 mg/dL / (11.1 mmol/L)	Two or more after 75g glucose loading
HbA1c	≥6.5%	One measurement
RPG	≥200 mg/dL / (11.1 mmol/L)	One measurement with symptoms of hyperglycemia

Table 2: Criteria for the Diagnosis of Diabetes (Kharroubi et al. 2015; ADA, 2009).

The disadvantage of the fasting plasma glucose test includes the need to abstain from food and drink for 8 hours prior to phlebotomy procedure and that there is a 12-15% day-to-day variance in fasting blood glucose values (Patel et al. 2010).

The OGTT is considered a first-line diagnostic test. Limitations of this test include poor reproducibility and the need for patient compliance as an eight-hour fast is needed before the 75-g glucose load, followed by drawing blood two hours later (Patel et al., 2010). The total prevalence of pathologic glucose metabolism was substantially higher based on HbA1c values than based on OGTT (Hjellestad et al. 2013).

Diabetes Mellitus may also be diagnosed with RBG level of 200 mg / dL (11.1 mmol / L) or higher if classic symptoms of diabetes, such as polyuria, polydipsia, weight loss, blurred vision and fatigue, are existing. Lower RBG values as 140 - 180 mg / dL (7.8 - 10.0 mmol / L) have a fairly high specificity of 92-98%; thus, patients with such values should undergo more definitive testing. A low sensitivity of 39-55% limits the use of RBG testing (Patel et al. 2010).

HbA1C values have currently been permitted by the ADA as a screening and diagnostic measurement for DM. One advantage of using this test is that it does not require fasting. However, it should be performed in a clinical laboratory because of the lack of standardization of point-of-care testing. Limitations of HbA1C testing include low sensitivity, possible racial disparities, and interference by anemia and some medications such as high-dose salicylates, vitamins C and E, and severe iron deficiency have been reported as interfering substances (Patel et al. 2010) (Saudek et al 2008).

Numerous difficulties impede the effort to diagnose diabetes. First, screening for diabetes in asymptomatic individuals is now suggested only by questionnaires to appraise risk or by FBG or OGTT, both of which require that the patient must fast for at least 8 hours beforehand (Saudek et al. 2008).

Despite its limitations, a sequence of practical considerations supports the use of HbA1c in screening and diagnosing diabetes, as the patient is not required to fast beforehand and its level is not affected by short-term lifestyle changes. The lack of availability of HbA1c in more remote places as well as the cost of the tests are reasonable concerns (Saudek et al. 2008).

Ealovega et al. in 2004 studied an opportunistic screening of non-diabetic patients ≥45 years of age in routine clinical practice at University of Michigan Health System that were enrolled in the health maintenance organization for a period of 3 years. The study found RBG to be the most common screening method (95%); which is the least sensitive test. In their survey, only 3% of screenings used FBG, 2% used HbA1c, and less than 1% used OGTT. RBG method was more feasible than FBG and OGTT because in clinical practice, patients could be seen at any time of day without the need to fast beforehand.

Bowen et al. in 2015 found that single RBG of 5.6 mmol/L or more is strongly associated with undiagnosed diabetes than traditional risk factors. Abnormal RBG levels are a risk factor and considered in diabetes screening guidelines.

The accuracy of RBG results is a consideration. Though point-of-care capillary blood glucose measurement is more rapid, less invasive and cost-effective than laboratory measurement of blood glucose concentration, the latter is considered to be the most accurate method.

A substantial number of people with diabetes are undiagnosed, possibly due to the variable asymptomatic, latent period during which the disease cannot be clinically detected. Despite this subclinical presentation the numerous immediate effects accumulate with severe long-term complications, such as cardiovascular events (Stolk, 2007). Thus screening and early detection of diabetes is vital.

A study by Beagley et al. in 2014 revealed that 45.8% or 174.8 million adult diabetes cases are speculated to be undiagnosed, ranging from 24.1% to 75.1% across data regions. The highest proportion of this percentage was found in low and middle-income countries, which account for 83.8% of all UDM cases. The study concluded that there was a high proportion of undiagnosed diabetes globally, mostly in developing countries. Furthermore, high quality studies of UDM are needed to strengthen future estimates.

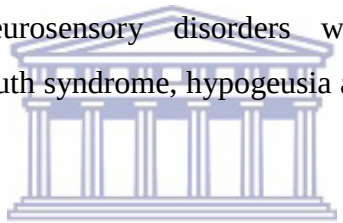
It is obvious that screening for and detection of undiagnosed diabetes is very important. Patients with new high blood sugar levels had a higher in-hospital mortality (16%) compared to patients with a known history of diabetes (3%) and normal glycaemia (1.7%; both $P < 0.01$), which indicates that new hyperglycemia represents a marker of a more severe illness (Umpierrez et al. 2002). These patients were unaware of their diabetic status and were admitted to hospital for complications related to their undiagnosed diabetes.

Umpierrez et al. 2002, found hyperglycemia to be present in 38% of patients admitted to hospital, of which one third was not aware of their diabetic status prior to admission. Patients with unknown diabetes, which diagnosed once admitted to the hospital, had significantly higher rate of in-hospital mortality and worse functional outcome compared to patients with a previous history of diabetes or subjects with normal glycaemia. In

addition to that, newly diagnosed diabetic patients had a longer hospital stay, were more likely to require an ICU admission and on discharge, were more likely to need referral to a transitional care unit or nursing home facility (Umpierrez et al. 2002). These observations support the fact that hospitalized patients should be screened for high blood sugar levels on admission.

2.4- Diabetes Mellitus and oral health

There is a strong relationship between oral health and diabetic status. Poorly controlled diabetics are susceptible to dental problems such as gingivitis, periodontitis, recurrent periodontal abscess, delayed healing after extraction, dry socket, oral infections like *candidiasis*, xerostomia, neurosensory disorders which result in glossodynia, stomatopyrosis or burning mouth syndrome, hypogeusia and other oral dysesthesias (Jha et al. 2014).



Evidence supports the correlation between oral health and diabetes mellitus, reporting diabetic patients to have poorer oral hygiene than non-diabetic individuals (Ship, J.A., 2003) (Lamster et al. 2008). In Brazil, Silva et al. (2015) reported a higher prevalence of conditions such as gingivitis, periodontitis, mucosal diseases, hyposalivation or xerostomia, enlargement of salivary glands, loss of taste, and burning mouth, in diabetic patients, most of which are associated with type 2 diabetes.

Oral health awareness is lacking in diabetic patients and auxiliary health staff. Thus, physicians in both dental and medical fields should be educated about the varied oral manifestations of diabetes, to facilitate early diagnosis and referral. A study in Saudi Arabia (Bahammam, 2015) revealed the need to implement education programs in communities with/without diabetic patients. According to Basak Cinar et al. in 2014, health coaching compared to formal education, is more important for the diabetic patients to improve management of both their diabetes and oral health.

2.5- Diabetes Mellitus and soft tissue lesions

Guggenheimer et al. I in 2000 conducted a study comparing the incidence of insulin-dependent diabetes mellitus and oral soft tissue pathologies. The study reported that oral soft tissue lesions, three of which were non-*candidal*, such as fissured tongue, irritation fibroma, and traumatic ulcers had a higher prevalence rate in diabetic patients. The latter two are suggested to be associated with delayed healing, trauma or both. They found no significant difference between diabetic and non-diabetic patients related to lichen planus, gingival hyperplasia, or salivary gland disease.

Candida associated oral soft tissue lesions, such as median rhomboid glossitis, denture stomatitis and angular cheilitis, were more frequently recorded in diabetic patients. Oral candidiasis was the most prevalent soft tissue lesion, aggravated by cigarette smoking, use of dentures and poor glycemic control (Guggenheimer et al. II 2000).

Leite et al. in 2013 reported type 2 diabetes to be associated with certain oral mucosal diseases. These included a high rate of fungal infections, like oral *candidiasis*, fissured tongue, traumatic ulcers, irritation fibroma, recurrent aphthous stomatitis and lichen planus. These conditions maybe due to delayed healing, chronic immunosuppression and/or salivary gland dysfunction.

In addition, Al-Maweri et al. in 2013, prevalence study of soft tissue lesions in type 2 diabetic patients in Malaysia, found the prevalence of oral mucosal lesions, such as geographic tongue, denture stomatitis, angular chelitis and xerostomia, to be higher in diabetics than in non-diabetic patients. These were significantly related to poor metabolic control.

3- Research Design and Methodology

3.1- Aim:

To assess the diabetic status of patients presenting for dental treatment at the Maxillofacial Outpatient Department at Tygerberg Hospital.

3.2- Objectives:

1- Assess the incidence of undiagnosed diabetes mellitus

2- Determine the prevalence of diabetes mellitus in patients presenting for dental treatment.

3- Describe associated intraoral soft tissue lesions.

3.3- Study design:

Cross-sectional observational study in patients presenting for treatment at the Maxillofacial Outpatient's Department at Tygerberg Hospital.

3.4.- Inclusion criteria:

Adults > 18 years of age.

3.5- Exclusion criteria:

1- Children and adolescents <18 years of age.
2- Patients who are unable to open their mouth for any reason and who have sepsis.
3- Pregnant women.

3.6- Sample size:

The sample size (*n*) was 400 to ensure a 95% confidence interval.

3.7- Study Site and Sample selection procedure:

Participants were selected from consecutive adult persons presenting at the Maxillofacial department at Tygerberg Hospital.

Persons who met the inclusion criteria and were willing to participate were included in the study until the required number was attained.

All participants were briefed about the study and informed consent was obtained.

3.8- Data collection time:

Blood sample collection was obtained in the morning while patients were waiting for treatment.

3.9- Materials:

- Blood glucose monitoring device (Accu-Chek Active Blood Glucose Monitoring Device).
- Blood glucose test strips (Accu-Chek).
- Lancets.
- Mirrors and gloves.
- Antiseptic solution and cotton swabs.

3.10- Method used for sample collection:

Blood sample collection:

1- All participants were advised to rinse their hands with water and antiseptic solution beforehand.

2- The side of the fingertip was lanced using the lancing device.

3- A blood drop was applied to the test strip and inserted into the blood glucose monitor.

3.11- The blood glucose level for random and fasting blood glucose - (mmol/L).

Random Blood Glucose

The normal RBG level is between 4.4 - 7.8mmol/L (79 - 140 mg/dL).

Pre-diabetes is between 7.8mmol/L and 11.1mmol/L (between 140mg/dl and 200 mg/dL).

Diabetes is 11.1mmol/L and above (200 mg/dL and above) (Diabetes 2014).

If the blood glucose is higher than 8.7mmol/L, the patient was referred to the day hospital to measure HbA1C.

	Random Blood glucose	
	mg/dL	mmol/L
Normal	79 - 140 mg/dL	4.4 - 7.8mmol/L
Prediabetic	140 - 200 mg/dL	7.8 - 11.1mmol/L
Diabetic	200 mg/dL and above	11.1mmol/L - above

Table 3: Random blood glucose levels

Fasting Blood Glucose

The normal FBG level is between 3.9 – 5.6mmol/L (70 - 100 mg/dL).

Pre-diabetes is between 5.6mmol/L and 6.9mmol/L (between 100mg/dl and 125 mg/dL).

Diabetes is 7mmol/L and above (126 mg/dL and above).

If the blood glucose was higher than 7mmol/L, the patient was referred to the day hospital to measure HbA1C.

	Fasting Blood glucose	
	mg/dL	mmol/L
Normal	70 - 100 mg/dL	3.9 – 5.6 mmol/L
Prediabetic	100 - 125 mg/dL	5.6 – 6.9 mmol/L
Diabetic	126 mg/dl and above	7 mmol/L - above

Table 4: Fasting blood glucose levels

3.11- Data analysis:

The data collected was recorded on a data collection form, transferred to an Excel® spread sheet and analyzed by a statistician using the same program.

3.12- Ethical considerations:

The study was carried out after obtaining ethical approval from the Research Ethics Committee of the University of the Western Cape.

The study procedure was non invasive and not harmful to participants and the confidentiality of participants was preserved.

Informed consent was obtained from all the participants after explaining the aim of the study and the method of its application. The ethics approval number was 15/7/40.

4-The Results

The study comprised *n* =400 participants, of whom 38.5% were male and 61.5% were female. Their age range was 18 to 81 years with a mean of 39.8 years. The respondents below the age of 40 comprised 56.2%, 31% were between 41 and 60 years and 12.7% above the age of 60 years. The age and sex distribution of the sample are presented in Table 5.

Age	**Sex**		**Total** N (%)
	Female N (%)	Male N (%)	
< 40 years	137 (34.2%)	88 (22%)	225 (56.3%)
41-60 years	81 (20.2%)	43 (10.7%)	124 (31%)
> 61 years	31 (7.8%)	20 (5%)	51 (12.7%)
Total	249 (62.2%)	151 (37.7%)	400 (100.0)

Table 5: Sample age and sex distribution

Patients were categorized into 3 groups based on blood glucose levels: normal, pre-diabetic and diabetic. Of the subjects aged below 40 years, 7 (1.8%) were prediabetic and 7 (1.7%) were diabetic. Among participants aged between 41-60 years, 3 (0.8%) were prediabetic and 21 (5.2%) were diabetic, whereas, 1 (0.2%) prediabetic and 12 (3%) diabetic subjects were above 60 years of age [Table 6].

Age	**Normal**	**Prediabetic**	**Diabetic**	**Total**
< 40 years	34 (8.5%)	7 (1.7%)	7 (1.8%)	48 (12%)
41-60 years	98 (24.5%)	3 (0.8%)	21 (5.2%)	122 (30.5%)
> 61 years	217 (54.2%)	1 (0.2%)	12 (3%)	230 (57.5%)
Total	349 (87.2%)	11 (2.7%)	40 (10%)	400 (100.0)

Table 6: Distribution of diabetes and prediabetes among sampled population by Age

Blood glucose measurements were obtained from 309 and 91 patients using the Random blood glucose method and fasting blood glucose method respectively. Patients were categorized into 3 groups based on blood glucose level: normal (*n*=349), pre-diabetic (*n*=11) and diabetic (*n*=40), which summarized in Table 7.

	Normal		**Prediabetic**		**Diabetic**	
	Random	Fasting	Random	Fasting	Random	Fasting
	269	80	6	5	34	6
Total	349		11		40	

Table 7: Overview of blood glucose readings for *n*=400 patients

Of the 400 patients included in the study,

- The prevalence of diabetes was 10% (*n*= 40).
- The incidence was 1% (*n*=4).
- Prediabetic patients accounted for 2.7% (*n*= 11).

In total 51 (12.7%) out of 400 were either known diabetic patients or newly diagnosed (prediabetic and diabetic) and 15 (29.4%) out of these 51 patients are unaware of their status (undiagnosed).

Table 8 shows the blood glucose levels (normal, prediabetic and diabetic) for the fasting group. Seven (7.6%) out of 91 patients were referred for diabetes testing.

		Diabetic status		Total
		Known	**Unknown**	
Normal	<5.6	0	80	80
Prediabetic	5.6-6.9	0	5	5
Diabetic	>6.9	4	2	6
Total		4	87	91

Table 8: Blood glucose values for the fasting group

In 91 patients the time between food intake and blood glucose measurement was a minimum of 8 hours and their blood glucose measurements were categorized as FBG. Five patients (5.4%) had FBG measurements between 5.6 and 6.9 mmol/dl and 6 (6.5%) had FBG measurements of > 6.9 mmol/L. Four (4.3%) of known diabetic patients had a FBG of > 6.9 mmol/L.

Table 9 shows the blood glucose levels (normal, pre diabetic and diabetic) obtained from the RBG group. Eight (2.5%) patients were referred for diabetes testing.

mmol/L		**Diabetic status**		**Total**
		Known	Unknown	
Normal	<7.8	12	269	281
Pre diabetic	7.8-11.1	9	6	15
Diabetic	11.1->	11	2	13
Total		32	278	309

Table 9: Blood glucose values for the random group

In the RBG group, 15 (4.8%) patients had blood glucose measurements between 7.8 and 11.1 mmol/L and 13 (4.2%) had blood glucose readings of >11.1 mmol/L.
Thirty-two (10.3%) patients were known diabetics and 8 (2.5%) out of 309 patients were referred for confirmation of their diabetes status (6 prediabetic, 2 diabetic).

Soft tissue lesions, *Candida* and smoking

Soft tissue lesions were recorded in 160 patients, 23(18%) of whom had above normal blood glucose levels. The range of soft tissue lesions seen is summarized in Table 10. Clinically evident Oral *Candidiasis* was seen in 64/137 patients with normal blood glucose levels and 14/23 patients with elevated blood glucose levels. Forty-five participants with blood glucose levels above normal (prediabetic and diabetic) had soft tissue lesions, 27.4% of which was oral *candidiasis*. On the other hand, of the

participants whose blood glucose readings were within the normal range, 39% had soft tissue lesions, 18% of which was oral *candidiasis*.

	Normal		Prediabetic		Diabetic	
	Random	Fasting	Random	Fasting	Random	Fasting
Soft lesions	112	25	4	2	14	3
Candida	50	14	2	2	8	2

Table 10: Overview the soft tissue lesions in normal, prediabetic and diabetic group

In FBG group, clinically evident soft tissue lesions were recorded in *n*=30/91 (32.9%) patients, 50% of whom had blood glucose levels > 7 mmol/L (40% were in the prediabetic range and 31% had normal blood glucose levels). Oral *candidiasis* accounted for 33.3%, 40% and 17.5% of these soft tissue lesions in the diabetic, prediabetic and normal group respectively.

In the RBG group, clinically evident soft tissue lesions were recorded in *n*=140/309 (45%) patients, of whom 41% had blood glucose levels > 11 mmol/L (66.6% were in the prediabetic range and 41.6% had normal blood glucose levels). Oral *candidiasis* accounted for 23.5%, 33% and 18% of these soft tissue lesions in the diabetic, prediabetic and normal group respectively.

Soft tissue lesions were recorded in 42.5% (*n*=17) of all diabetic patients (*n*=40), compared to non-diabetic individuals 39.2% (*n*=137 out of 349). Of the 17 patients who have soft tissue lesions, 13 (76%) had blood glucose levels >15 mmol/L. Oral *candidiasis* was recorded in 25% (*n*=10) of diabetic compared to non-diabetic participants 18.3% (*n*=64 out of 349).

Of the 51 hyperglycemic patients, 45% (*n*=23) had soft tissue lesions; 23.5% (*n*=12) had oral *candidiasis*, compared to the 18.3% of patients with normal blood glucose levels.

Data analysis showed that 103 (25.7%) of 400 patients wore dentures. Oral candidiasis was evident in 12.5% of diabetics who wore dentures.

Other soft tissue lesions recorded included fissured tongue (17.5%), geographic tongue (4%), irritation fibroma (4%) and traumatic ulcers (4%).

5- Discussion

The purpose of the study was to evaluate the incidence of undiagnosed diabetes mellitus, determine the prevalence of diabetes mellitus in patients presenting for dental treatment, and describe associated intraoral soft tissue lesions.

The sample comprised *n*=400 participants, whose ages ranged between 18 - 81 years, with a mean of 39.8 years. Most respondents were female aged between 18-40 years. The age range and gender profile of this study was comparable to one in rural North India (Thomas et al. 2015), in which 59.2% of participants were below the age of 40 years, 32.2% were between 41 - 60 years and 8.6% above 60 years of age.

Previous studies largely only screened people 40 years and older, but recent studies (Reinehr, T., 2013; Ramachandran, A., 2002; Thomas et al. 2015; Bailey et al. 2016) have included and subsequently diagnosed patients below 40 years with Type II diabetes mellitus. In the present study, the percentage of prediabetic patients was the highest below 40 years of age. Prediabetic states have been shown to progress to diabetes mellitus in 2-10 years when no intervention is put in place (Fonseca, V.A., 2008). This supports the inclusion of screening a broader age range for investigation in our study, to facilitate early diagnosis and thereby intercept undiagnosed chronic exposure to hyperglycemia and its long-term cumulative effects.

In the present study, the greatest proportion of diabetic patients was seen in participants older than 40 years of age. This was expected and comparable with other studies (Thomas et al. 2015; Shaw et al. 2010), which revealed a higher rate of diabetes between ages of 40 and 60 years.

This study revealed that the incidence of undiagnosed diabetes mellitus was 1.0%. This is comparable to other studies in which incidence estimates of 1.2% and 1% were reported in Western Cape and Zambia respectively (Bailey et al. 2016), despite the

study's smaller sample size. By comparison to the study in rural India (Thomas et al. 2015), the incidence of diabetes was 2.9%. The higher percentage of newly diagnosed patients could be related to the previous exclusion of patients younger than 40 years of age from diabetes screening programs. It is known that persons of Indian decent reportedly have the highest proportion of diabetes (Ramachandran, A., 2002), thus exclusion of possible prediabetic patients precluded them from early intervention strategies. Incidentally, the proportion of prediabetic participants in the Indian study (Thomas et al. 2015) was very high (10.6%) compared to our study findings. In the present study, ethnicity was not taken into account in the present study.

The prevalence of diabetes mellitus in this study was 10%. This is higher than prevalence values in a Western Cape and Zambian study (Bailey et al. 2016), which were 7.2 % and 3.5% respectively. The latter study was large and included 8 communities within the Western Cape and 16 communities in Zambia. In our study, the sample size was considerably smaller and the geographical area was limited, thus the high prevalence values may be reflective of the lack of education of high blood glucose levels in general.

In healthy individuals blood glucose levels do not vary widely throughout the day (Healthwise Staff, 2015), because the body's hormones (insulin and glucagon) work synergistically/ in sync to prevent plasma glucose levels from going too high or low. Blood glucose levels higher than 11 mmol/L may indicate a problem when measuring RBG. In this study two different tests were used to measure glycemic status, namely, FBG and RBG, both measured a single episode of glucose exposure and used for screening purposes. These findings were used to facilitate referral of at risk patients to measure HbA1C levels or provide dietary counseling. The former provides information for the average of 3 months plasma glucose exposure.

In total 51 (12.7%) out of 400 patients were either known diabetic patients or newly diagnosed (prediabetic and diabetic) and 15 (29.4%) out of these 51 patients are unaware of their status (undiagnosed). All patients screened whose blood glucose readings were

above normal were referred for confirmatory tests to measure their HbA1C. Previously known diabetic patients with elevated above normal glycemic readings were also refereed to their doctors for further evaluation.

The range of soft tissue lesions seen in prediabetic and diabetic patients were *candida* 27.4%, fissured tongue 17.5%, geographic tongue 4%, irritation fibroma 4%, traumatic ulcer 4%. Other soft tissue lesions were too few for any inferences to be made with regard to their presence and diabetic status. The study revealed that 42.5% (*n*=17) of diabetic patients (*n*= 40) had a soft tissue lesion, which was higher than in those with normal blood glucose levels 39.2% (*n*=137 out of 349) and 25% (*n*=10) of patients who were diabetic had oral *candidiasis*, compared to those with normal blood glucose levels 18.3% (*n*=64 out of 349).

In total, 45% of prediabetic and diabetic patients (*n*=23 of 51 patients) had soft tissue lesions, 27.4% (*n*=14 of 51 patients) of which had *candidiasis.* This was greater than in participants with normal blood glucose measurements. Denture wearing, smoking and inadequate oral hygiene could be additional predisposing factors. Similarly, a Malaysian study (Al-Maweri et al. 2013), also found the prevalence of oral mucosal lesions to be higher in diabetic patients (45.5%). It has been reported that poor glycemic control predispose to oral *candida* infection oral, which occurs with increased frequency in patients with diabetes mellitus (Soysa et al. 2006).

Early diagnosis would allow management to prevent or delay development of diabetes and its complications and thereby reduce associated diabetic related costs. Chatterjee et al. in 2010 revealed that screening seems to be cost saving compared to not screening from a health system perspective, and potentially cost-neutral from a social assessment. Our study findings recommend that attention should be paid to early screening for diabetes mellitus.

6-Conclusion

In conclusion, diabetes is one of the most widespread diseases and its prevalence is increasing significantly. Furthermore, it has a definite relationship with oral health.
Screening enables early diagnosis of individuals who are unaware of their diabetic status and also identifies persons at risk for future development of the condition. Screening thereby facilitating early management for both at risk and diabetic persons and is likely to be less than the cost of the subsequent treatment. RBG testing method is easier, more rapid, cost-effective and less invasive than laboratory measurement of plasma glucose concentration.

7- Recommendation

Further, this study co-incidentally demonstrates the potential of public health facilities, such as dental clinics, for screening of various conditions of public health concern such as Diabetes, HIV and Tuberculosis.
RBG is a useful method to screen for prediabetes and diabetes to facilitate referral of patients to measure HbA1C.

8- Limitation

This review has some limitations. The sampling of the subjects and selection of geographical area was influenced by programming concerns and so may not be representative of trends in the country. For the same reason, RBG was used more than fasting blood glucose, which is a more sensitive indicator.

It is well documented that most prevalent oral disease associated with diabetes is periodontal disease, which was not evaluated in this study. That was for many reasons; firstly the study was a screening for the prevalence and incidence of diabetes as the aim of this study was to assess the diabetic status of patients presenting for dental treatment. In addition, the study was done in maxillofacial department in which patients came mostly for extractions and there was not a chance to check the periodontal status and likely less acceptable to potential participants regarding to time and patients concerns to lose their appointments.

The ethnicity was not included in this study due to some ethical consideration.

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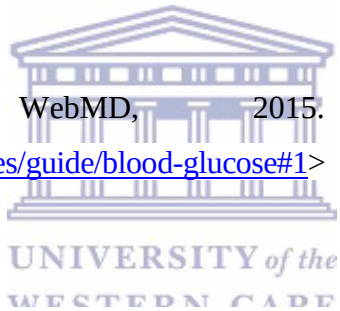

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Appendix 1

Data Collection Sheet

Record No.	…….	
Date	…….…….	
Gender	M…….	F……
Age	……..	

Smoke	Yes……...	No……	No/ Day…….
	Others……		
Alcohol	Yes…….	No……..…	No/ Day/Weekends……..
Medical History	……..		

Diabetic Status	Known: Yes……		No……	Last Check…….
Blood Glucose level	……. mmol/L		Time……am/pm	
Known Status	Well controlled……		Poorly controlled…….	
Medication	Yes……...	No……	Type……	
Last Food (Type)	……..			
Sugar (If added)	……...		**Time**……..…am/pm	

Denture	Yes…….	No……..
Type	For how long……..	
Missing Teeth	Yes. ……	No……..
The missing teeth	……	
Caries Teeth	Yes……..	No……..
The caries teeth	…….	
Dry mouth	Yes……..	No……..
Soft Tissue lesions	Yes…….	No……...

Soft Tissue Lesions

No.	Soft tissue lesion	Appearance and Symptoms	Yes	No
1-	Candidiasis			
	-Pseudomembranous (Thrush)	Creamy-white plaques, removable, burning sensation, foul taste.		
	-Acute atrophic candidiasis	Red macules, burning sensation, follows a course of broad-spectrum antibiotic, diffuse loss of filiform papilla		
	-Central papillary atrophy (Median rhomboidal glossitis)	Red, symmetric, atrophic mucosal areas; asymptomatic, affects the midline and surface range from smooth to lobulated.		
	-Angular cheilitis	Red, fissured lesions, irritated, raw feeling; usually with low vertical dimension of occlusion		
	-Denture stomatitis	Red, asymptomatic and may accompanied by petechial hemorrhage		
	-Hyperplastic (candidal leukoplakia)	White plaques that are not removable by scraping, asymptomatic		
2-	Fissured tongue	Multiple grooves or furrows, ±2-6mm, on the surface of the tongue, asymptomatic		
3-	Geographic tongue	Multiple, well-demarcated zones of erythema, elevated yellowish-white, serpentine or scalloped borders		
4-	Irritation fibroma	Smooth-surfaced pink nodule, sessile or pedunculated, asymptomatic,±1.5cm		
5-	Traumatic ulcer	Erythema surrounding a central removable, yellow fibrino-purulent membrane; rolled white border of hyperkeratosis with area of ulceration		
6-	Recurrent aphthous ulcers	Erythematous macule develops ulceration covered by yellowish white, removable fibrino-purulent membrane and encircled by erythematous hallo; may preceded by burning, itching, or stinging		
7-	Any other lesion			

Appendix 2

INFORMED CONSENT

Good day

I am Dr. **Marwa Negi,** carrying out a research project for a Master's degree in the Oral Medicine at the University of the Western Cape.

I would like you to participate in my study, which aims to determine the prevalence of diabetes in patients presenting for dental treatment.

This will be done by take blood from a finger drop.

You are completely free to decide whether to participate in the study or not and your decision will not negatively impact on your receiving treatment at this facility.

Please feel free to contact me if you have any queries or require additional information.

Sincerely

Dr. Marwa Negi

Cell Phone: 0613442707

I accept that the purpose and procedure of this study has been explained to me and I agree to take part in it.

I also understand that enrollment in the study will be anonymous and the results will be published for the benefit in the medical and dental fields.

Name: _____ Signature……..…

Phone No:……...…… Date: / /2016