

The prevalence of impaired glucose tolerance, impaired fasting glucose and undiagnosed type 2 diabetes among middle aged adults attending the outpatients department at the Professor ZK Matthews Hospital, Barkley West, Northern Cape Province; South Africa

by

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Declaration

I declare that the mini-dissertation hereby submitted to the University of Limpopo, for the degree of Master of Public Health has not previously been submitted by me for a degree at this or any other University; that it is my work in design and in execution, and that all material contained herein has been duly acknowledged.

KITENGE, TG (Doctor)

Date: 24 September 2014

Dedication

This work is dedicated to my father:

Professor Kitenge Kia Kayembe Charles

And mother

Maman Ilumba Godelive Kavula

To my wife

Lupona Rebecca Kitenge

To my son

Kia Kayembe Jonathan Kitenge

And

To my daughter

Ilumba Keren Kitenge

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Thanks to my wife, Rebecca Kitenge; thanks to my son, Jonathan Kitenge; and thanks to my daughter, Keren Kitenge.

Acronyms and abbreviations

| | |
|---------------|--|
| ADA | American Diabetes Association |
| BMI | Body Mass Index |
| DM | Diabetes Mellitus |
| FPG | Fasting Plasma Glucose |
| IDF | International Diabetes Federation |
| IFG | Impaired Fasting Glucose |
| IGT | Impaired Glucose Tolerance |
| OGTT | Oral Glucose Tolerance Test |
| PZKMH | Professor ZK Matthews Hospital |
| SEMDSA | Society for Endocrinology, Metabolism and Diabetes of South Africa |
| T2DM | Type 2 Diabetes Mellitus |
| 2-H PG | Two-hour Plasma Glucose |
| UD | Undiagnosed diabetes |
| WC | Waist Circumference |
| WHO | World Health Organisation |
| WHR | Waist-to- Hip Ratio |

Definition of terms (Adapted from DJ Soita)

- Anthropometric:** It is the measurement of body size, weight and proportion
- Alcohol:** An intoxicating chemical substance formed by the action of natural or added yeast on sugar grapes during fermentation. It is expressed as percentage of volume or weight.
- BMI:** Body Mass Index is a method used to measure whether a person is overweight or obese. It is calculated as weight (kg) divided by height (m) square.
- Cardiovascular:** Pertaining to the heart and blood vessels.
- Developing countries:** A nation where the average income is much lower compared to the highly industrialised and developed countries.
- Fasting Glucose:** A blood test done to determine the blood sugar level in a fasting state (not eaten for 8 – 12 hours).
- Glucose:** A simple sugar that is the body main source of energy. When absorbed into the blood stream, it requires insulin so as to provide energy to the body cells
- Hyperglycaemia:** Excessive blood glucose concentrations - a sign that diabetes is not well controlled
- Insulin:** A hormone secreted by the pancreas and which helps to regulate carbohydrate metabolism
- Insulin resistance:** A condition in which the body does not respond normally to the action of insulin.
- Metabolism:** The physical and chemical process by which substances are produced or broken down into energy or products for the use of the body.

Obesity: A condition of being extremely over weight. It is defined by having a BMI of over 30.

OGTT: Oral Glucose Tolerance Test - a test of the body ability to utilise carbohydrates. It is performed by giving a standard dose of solution and measuring the blood for glucose level after two hours.

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Abstract

Objective: The purpose of this study was to determine the prevalence of impaired glucose tolerance, impaired fasting glucose, undiagnosed type 2 diabetes and its associated risk factors among adults patients attending the outpatient department of a level one hospital in a rural community of Barkley West, South Africa.

Research methodology: This was a cross-sectional survey conducted by a simple random sampling of adults patients ≥ 30 years old. Patients were screened using the American Diabetes Association and the World Health Organisation criteria. First, patients underwent the 75g oral glucose tolerance test and secondly, the 12-hours fasting plasma glucose tests after pre-test results of 5.5 mmol/L were obtained considered as positive for screening. To determine the prevalence of IGT, IFG, and undiagnosed type 2 diabetes; tests were conducted using both the capillary finger puncture and the laboratory methods. To ensure validity and reliability, each patient underwent two tests (fasting and random) by the capillary finger puncture method and two tests (fasting and random) by the laboratory method.

Results: Eighty-five (85) questionnaires were distributed, supervised and returned by a research assistant, which brought the response rate to 100%. All patient known living with diabetes mellitus was not included in the study. The prevalence of IGT was 34.1% [34% for females and 9.4% for males] and that for IFG was 23.6% [25% for females and 6.0% for males]. The prevalence of undiagnosed type 2 diabetes discovered during the survey was 9.3% by 2-hours 75g glucose tolerance test [8.2% for females and 1.1% for males] and that by 12-hours fasting plasma glucose, the prevalence was 5.8% [4.7% for females and 1.1% for males]. The associated risk factors were physical inactivity, overweight and obesity, unhealthy diet, alcohol consumption, hypertension, smoking habit, family history of diabetes, social deprivation and poverty. The prevalence of hyperglycaemia was also high among female patients due to a higher BMI with 25% overweight (females 18% overweight, males 7% overweight) and 75% obese (females 54% of obesity, males 21% of obesity); higher waist circumference with higher abdominal fat (females 71.7% had a W/C ≥ 88 cm, males 28% had a W/C ≥ 102 cm.); and a larger waist-to-hip ratio (females 61.1% had WHR > 0.85 , males 7% had a WHR > 1.0). The sensitivity, specificity, positive and negative predictive values for IGT were 34%, 86%, 25%, and 86% and those for IFG were 24%, 86%, 19%, and 86% respectively. IGT sensitivity was greater than IFG sensitivity.

Conclusion: There was a high prevalence of IGT, IFG and undiagnosed type 2 diabetes specifically among female patients. The ten percent difference of sensitivity between the two tests showed that the WHO diagnostic criteria produced more patients with the pathology than the ADA diagnostic criteria do. Patients attending the outpatient department of a level one hospital in Barkley West are at high risk of developing type 2 diabetes and remain unidentified, undetected, unscreened, undiagnosed and untreated. Obesity at primary health care level in the rural community of Barkley West needs to be addressed.

. **Keywords:** Impaired glucose tolerance, prevalence, diabetes, screening, anthropometric measurements.

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CHAPTER 1: Overview of study

1.1 Introduction

Impaired glucose tolerance (IGT), along with impaired fasting glucose (IFG) is a pre-diabetic state of hyperglycaemia that is associated with insulin resistance. This means that blood glucose level is consistently elevated above what is considered normal levels; however, it is not enough to be diagnosed as diabetes mellitus (Barr, 2007). Pre-diabetic state can progress to type 2 diabetes mellitus over 10 years if lifestyle changes are not made and also increases the risk of cardiovascular pathology (Nichols, 2007).

According to the International Diabetes Federation (IDF) it is estimated that worldwide 344 million people aged 20-79 are living with IGT and IFG, but the majority (70%) with these conditions are living in low-and middle-income countries. Africa accounts for 29.7 million people living with impaired glucose tolerance and it is the most affected continent, as it is also experiencing an ever-increasing burden of diseases, among which are infectious diseases such as malaria, T.B and HIV (IDF, 2013).

South Africa (SA) is not immune to this as the epidemic of obesity is linked to a high prevalence of hyperglycaemia like IGT and undiagnosed type 2 diabetes mellitus. According to Ogunbanjo (2013) 61% of the SA populations were overweight or morbidly obese; also the country is placed third in the world in terms of obesity ranking after the USA and Great Britain. The epidemic of obesity in SA is due to a combination of excessively high energy food intake, physical inactivity, genetic susceptibility, endocrine disorder, and medications or psychiatric illness (Ogunbanjo, 2013). The levels of obesity and the nature of lifestyle show that impaired glucose tolerance in SA is already an epidemic.

1.1.2 Problem statement

The problem observed by the researcher at the outpatients department of Prof. ZK Matthews Hospital in the rural community of Barkley West, indicated that patients presenting with metabolic syndrome such as obesity, hypertension or dyslipidaemia; generally were not identified, not detected, not screened, not even diagnosed or treated, and also the anthropometric measurement generally is not done during the assessment or consultation. Therefore, there is missed opportunity of early diagnostic, early prevention and early intervention. It is well documented in previous studies that the pre-diabetic state is asymptomatic and

it is also called “silent killer”. In this condition, undiagnosed patients are mounting with the increase risk of long-term complications such as cardiovascular diseases (limbs amputation, kidney disease, stroke, peripheral venal insufficiency, myocardial infarction or acute coronary syndrome); neuropathy (impotency), hypoglycaemia, reduced or loss of vision, disability and death.

1.1.3 Rationale of study

The researcher decided to conduct the study as it is relevant to public health problem encountered at primary health care level in the rural communities of Barkley West. Also the study has an impact on the life of the local populations concern on the hyperglycaemic disorders and the subsequent association between their lifestyle and the long term complications of hyperglycaemia. Early screening of patients having the risk of developing type 2 diabetes mellitus has a significant clinical outcome in the reduction of morbidity, mortality and disability. The cost, the expenditure, and financial implications on the disease makes the department of health to pay a huge price if only clinicians were able to screen earlier, diagnose earlier, and also intervene earlier.

The study is important since it will help to gather appropriate information which will help to understand the context of substandard care of patients having the risk of developing impaired glucose tolerance, impaired fasting glucose or type 2 diabetes. The study will encourage health professionals to make use of guidelines and existing tools put in place for a good clinical practice and also increase the level of awareness and knowledge among patients through health education and health promotion. The researcher hoped that this study would achieve the following:

- To contribute to the body of knowledge on impaired glucose tolerance and risk of developing type 2 diabetes mellitus;
- To benefit physicians, nurse clinicians and nurse educators on screening, intervention, and prevention mechanisms;
- To implement guidelines of the Society of Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA), the World Health Organisation (WHO) or that for the American Diabetes Association (ADA);

- To train community health workers and health promoters in order to increase the level of awareness campaign on the epidemic of impaired glucose tolerance, impaired fasting glucose and undiagnosed diabetes in different communities of Barkley West;
- To reduce the epidemic of obesity by promoting ideal weight and physical activities among patients having the risk of developing hyperglycaemic disorders and to promote a healthier diet and nutrition.

Intermediate hyperglycaemia is now an epidemic in South Africa among middle-aged adults as a serious public health problem in the country. South Africa is among the first five countries in sub-Saharan Africa, with ever-increasing type 2 diabetes and impaired glucose tolerance. Overweight and obesity is also an epidemic in South Africa and constitute one of major factors in the aetiopathophysiology of the disease in addition to sedentary lifestyle, urbanisation, a diet rich in high energy and protein, lack of physical activity and genetic predisposition. All together is the sole foundation of the disease burden. These risk factors also come to add to others pre-existing diseases burden such as HIV, malaria, and tuberculosis.

The study is significant since the primary health care setting will be empowered with information on the importance of diabetes education and lifestyle modifications. The most important aspect of reducing risk is by reducing the epidemic of overweight and obesity as well as to identify individuals having the higher risk of developing type 2 diabetes. This may be possible by early screening, early diagnoses, early intervention and early prevention in order to curb the incidence and prevalence of type 2 diabetes mellitus before long term complications become visible.

1.3 Aim of the study

The aim of this study is to determine the prevalence of impaired glucose tolerance, impaired fasting glucose, undiagnosed type 2 diabetes, and associated risk factors among middle aged adults attending the outpatients department of Professor ZK Matthews Hospital.

1.3.1 Specific objectives of the study

- To described the socio-demographic characteristics of patients
- To determine the associated risk factors of intermediate hyperglycaemia,
- To determine the sensitivity, specificity, positive and negative predictive value of the test
- To determine the test that identified more patients with pre-diabetic state

1.4 Organisation of Mini-dissertation

The mini-dissertation is included the following chapters:

- Chapter 1: Overview of study, Chapter 2: Literature review, chapter 3: Methodology, chapter 4: Discussion, chapter 5: Results, and chapter 6: conclusion and recommendations

1.4.1 The overview of study

The introduction contains the following structure:

- Brief overview of the topic and its relevance
- Problem statement and rationale of study

1.4.2 The literature review:

This chapter reviews studies done on the topic in logic manner:

- Global studies, regional studies, continental studies and local studies

1.4.3 The methodology

The sub-heading under this section includes:

- Study design, study setting, and study population
- Inclusion criteria and exclusion criteria
- Study sample, data collection and data analysis

- Reliability and validity of the study
- Study bias and ethical consideration

1.4.4 The results

In this section the results of the study are produced. This is a simple descriptive analysis link to the main objective and to the specific objectives.

1.4.5 Discussion

The findings of the study are compared to the findings of studies done previously reviewed the literature review on the same topic. The differences, the similarities, gaps and improvement of the study are compared. The approach is systematic as global, regional, continental, and local studies.

1.4.6 Conclusion and recommendations

The findings of the study was used to draw the conclusion in the context of the study setting with a subsequence of recommendations to be put in place for the improvement of the health of the populations studied.

1.4.7 References

In this mini-dissertation the researcher make use of Harvard style of referencing.

1.4.8 Appendix

The research contains copies of approved consent form, leaflet of patient participation, MREC clearance certificate and the Northern Cape ethical committee prior to commence the study.

Chapter 2: Literature review

2.1 Epidemiology of IGT, IFG and undiagnosed T2DM

The number of people with impaired glucose tolerance worldwide will increase dramatically by more than half over the next 20 years, as projected from 316 million people in year 2013 to 471 million people by 2035 (IDF, 2013). This was translated as a prevalence of 6.9% of adults population with IGT or IFG by the year 2013 and has also been projected to 8.0% by 2035 worldwide. The report indicated that the vast majority of these people with IGT or IFG are living in the developing countries. Africa will contribute significantly to the increase of the disease (IDF, 2013).

In addition, the International Diabetes Federation also highlights that as many as 175 million people worldwide are not aware of their condition. No country in the world has diagnosed all people living with IGT, IFG or undiagnosed diabetes. The proportion of people with diabetes who are undiagnosed is as high as 90% in some countries, specifically in sub-Saharan Africa where resources are often lacking and screening of diabetes is not a priority (Evaristo-Neto, 2010).

Regionally, the prevalence of all people with undiagnosed diabetes in the South-East Asia (35.1 million of people) and the Western Pacific region (74.7 million of people), which was translated to 60%, but globally, 84% of all people who are undiagnosed live in low-and middle income countries (Plantinga, 2010).

The prevalence of impaired glucose tolerance is in the increase in South Africa too. The recently publication of the International Diabetes Federation (IDF, 2013) indicated that the prevalence of IGT in South Africa is 8.3% translated as 2.6 million South Africans aged between 20 and 79 in 2013. Gardner et al (2012) also point out that about 85% of South Africans with impaired glucose tolerance having the risk of developing type 2 diabetes mellitus are not diagnosed and not even aware of their health condition (Gardner, 2012).

The WHO estimates that by 2015 the number of overweight people worldwide will increase to 2.3 billion, while more than 700 million will be obese (WHO, 2010). The rise in the prevalence of impaired glucose tolerance, impaired fasting glucose, and undiagnosed diabetes; which accounts for the majority of cases of acute or chronic hyperglycaemia globally, has been linked to the increase in the prevalence of obesity (Ogunbanjo, 2013; Puoane, 2002).

2.2 Definition and Diagnostic criteria

The American Diabetes Association defined impaired glucose tolerance as two-hour 75-g oral glucose tolerance test values of 140 to 199 mg per dL (7.8 to 11.0 mmol per L); normal value on this test are below 140 mg per dl (below 7.8 mmol per L). Impaired fasting glucose is defined as fasting plasma glucose values of 100 to 120 mg per dL (5.6 to 6.9 mmol per L); normal fasting glucose values are below 100 mg per DI (Shobha, 2004).

WHO defined impaired fasting glucose as a fasting plasma glucose concentration which is greater or equal to 6.1 mmol per L and below 7.0 mmol per L and the impaired glucose tolerance is defined as a fasting plasma glucose concentration below 7.0 mmol per L and a two-hours post-load plasma glucose concentration greater or equal to 7.8 mmol per L and below 11.1 mmol per L measured during a 75-g of oral glucose tolerance test (Gardner, 2013).

2.3 Aetiopathophysiology of IGT

The presence of hyperglycaemia implicates defects in several organs. In the pancreas islet, impaired insulin secretion results from defects in the β -cells. In the liver, glucose production increases as a consequence of increased hepatic gluconeogenesis (Petersen, 2006). Complications is a result of metabolic disorder of multiples aetiologies characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism taking place from both defects insulin secretion and insulin action as a consequence of eye damage, renal failure, cardiovascular event, neuropathy, and stroke in the long-term (WHO, 1999).

Three stages describe the pathophysiology of impaired glucose tolerance in the trajectory of glycaemic change. First stage is the long duration of insulin resistance accompanied by a compensatory increased rate of insulin secretion and increased β -cell mass. The second stage is the stable adaptation period when β -cells are no longer fully compensating for increased insulin resistance. In the third stage of diabetes development, β -cells become unable to compensate for insulin resistance and consequently glucose concentrations start to increase rapidly (Tabak, 2012).

The pathophysiology hallmark of the disease is insulin resistance, which has both genetic and acquired components, and which is present in over 90% of patients. Glucose intolerance and hyperglycaemia supervene only when the pancreatic β -cells are unable to maintain compensatory hyperinsulinaemia to

overcome tissue resistance to insulin action, primarily in the liver and in the peripheral at the skeletal muscles and adipose tissues (Joshi & Joshi, 2008).

In addition to this; having hyperglycaemia and insulin resistance, over 80% of individuals with impaired glucose tolerance or undiagnosed type 2 diabetes are obese and have a host of metabolic abnormalities, including dyslipidaemia and hypertension contributing to the higher incidence of cardiovascular morbidity and mortality (Joshi, 2009).

According to Joshi (2008) the transition period that precedes hyperglycaemia is asymptomatic, silent and may take 8 to 10 years. Nathan (2007) estimated that the transition period may take 13 years, the Hoorn Study estimated between 5.8 to 6.5 years, the Italian study estimated at 11.5 years, and the Paris Prospective Study estimated at 30 months. This wide variation in reporting the transition period is probably due to the unknown length of time spent in the pre-diabetic state (Nathan 2007, Joshi, 2008).

2.4 Screening recommendations

There is insufficient evidence to recommend for or against routine screening of asymptomatic adults for type 2 diabetes, IGT, or IFG. Control of early diabetes as a result of screening provides additional benefit over waiting to treat until a clinical diagnosis has been made. Clinical judgment, patient preference, and selective screening is recommended and the screening interval of every three years in the absence of risk factors beyond age alone, whereas a shorter screening interval is recommended for personal high risk of developing the disease (Shobha, 2004).

There is no benefit in screening the entire population due to potential harms include labeling patients as having a chronic illness, which may cause anxiety and make it difficult for obtaining health insurance and subjecting patients to the risk of long-term treatment with uncertain benefits. In South Africa, the classification and the diagnostic criteria from the World Health Organisation and the American Diabetes Association are used. However; the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) also provides updated guidelines in this regard (Shobha, 2004; Joshi, 2008).

Most of people with IGT, IFG or diabetes live for years without realising that they have the disease and become evident only after developing complications such as neuropathy, cardiovascular disease, retinopathy, or nephropathy. Diabetes is a leading cause of new cases of blindness in adults 20-74 years of

age and also a leading cause of kidney failure or amputations. It is therefore very important to detect the disease early (Joshi, 2008).

2.5 Associated risk factors for IGT, IFG and undiagnosed diabetes

The International Diabetes Foundation (IDF, 2013) established that patients with impaired glucose tolerance or impaired fasting glucose have a significant risk of developing diabetes. This group is an important target for primary prevention. The major risk factors contributing to the development of IGT, IFG of undiagnosed diabetes are as follow:

- Family history of diabetes
- Body mass index greater than 25 kg per m²
- Obesity (central or morbidly)
- Inactivity (lack of exercises)
- Sedentary lifestyle
- Hypertension
- Dyslipidaemia
- High waist circumference and high Waist-to-Hip Ratio
- Poverty and socio-economic status

Obesity has become a burden on the health care cost; reducing quality of life with increased prevalence the disease. The Improvement of socioeconomic status and the adoption of more sedentary lifestyle as well as unhealthy dietary habit showed that impaired glucose tolerance and obesity is now leading public health concern even among the rural communities. Obesity is most linked to socio-cultural and behavioral factors, including eating pattern, as well as the lack of awareness or knowledge on the associated health risk (Mohamud, 2011).

Puoane et al (2002) reported that the perception of obesity in African tradition is very worrying; that being overweight has many positive connotations in the African communities of South Africa; that being obese is perceived to reflect affluence and happiness. It is also thought that for women, obesity reflects on a

husband ability to care for his wife and family, that obesity seen to reflect persons who are healthy, while it is predisposed to hyperglycaemic disorders in the South African populations.

Earlier studies conducted elsewhere established a strong association between obesity, modernisation, urbanisation, economic development and affluent lifestyle are causing high prevalence of IGT, IFG, and diabetes. A study conducted by Akhter et al (2011) on a rural Bangladesh population showed that the undergoing lifestyle transition due to socio-economic growth, road communication, electrification, and mechanised cultivation in current years which have change the rural lifestyle. The improvement of living conditions in rural area may be responsible for the observed high rate of prevalence of hyperglycaemic disorders. This was also observed in a study by Mehta (2011) in Nepal that hyperglycaemia was caused by a complex interaction of genetics, environmental factors and lifestyle choice, contributed to impaired glucose tolerance in addition to rapid urbanisation, widening income gaps and social inequalities are also majors risk factors.

Kasiam Lasi On'Kin (2008) in Kinshasa, the Democratic Republic of Congo reported that impaired glucose tolerance was in epidemic proportion. The associated risk factors were total obesity, central obesity, and rural-urban migration. Physical inactivity, smoking, high social class, high intake of animal fat, and high class level and high energy intake were independent risk factors. In urban and rural areas of Western India Shah (2013) reported that high BMI and high obesity were the major risk factors

In the Finnish population study, Saaristo (2008) reported that in addition to central obesity and high BMI, high waist circumference, and high waist-to-hip ratio were predictor indices of impaired glucose tolerance and undiagnosed diabetes with a prevalence of 42% and 50% respectively. In South Africa, Motala (2008) reported that high anthropometric status, high dyslipidaemia, and high alcohol ingestion were major risk factors for impaired glucose tolerance. The study showed that with 84.8% patients with diabetes among the population studied was discovered during the survey.

Mutebi (2012) and Erasmus (2012) reported that the high prevalence of non-diabetic hyperglycaemia was 83% and undiagnosed diabetes was 81.2%. The risk factors were associated with high prevalence of metabolic syndrome which was 60.6% including central obesity, elevated blood pressure, family history of diabetes, and dislipidaemia. Many others risk factors were also identified; poor diet habit, alcohol consumption, low level of physical activity, and smoking.

A study by Makinga (2013) in the Kingdom of Lesotho reported that the prevalence of obesity was due to high BMI, high waist circumference and high waist-to-height ratio. Sengwayo (2013) in the Capricorn district of Limpopo province also admit to the same conclusion. In 2007, the Medical Research Council found out that 56% of adults women and adults men in South Africa were overweight or obese. In 2010, GlaxoSmithKline also showed that 61% of the South African populations were overweight or obese.

2.6 Lifestyle intervention

A structured program of diet and exercise can reduce the risk of progression to type 2 diabetes mellitus in patients with impaired glucose tolerance and should be advised on the benefits of modest weight loss, good dietary habit with low-calorie intake, low fat, and moderately-intensity regular physical activity. Studies were conducted elsewhere to demonstrate the effectiveness of lifestyle interventions to reduce obesity and cardiovascular risks.

Joshi (2008) demonstrated that studies done previously have a strong evidence on successful and effectiveness of lifestyle intervention. In the Finnish Diabetes Prevention Study and the Chinese Da Qing Study, both studies have shown that people with impaired glucose tolerance can be prevented by making changes in the diet to promote moderate weight loss by increasing their level of physical activity. By doing so, in a case control study; there was a 58% relative risk reduction.

The Da Qing Study on a randomized control trial showed reduction in development of diabetes by 31% to 46% in a combination of diet control and exercise followed over 6 years. Type 2 diabetes can be delayed for up to 14 years after active intervention. The study also showed that 30 minutes per day of moderate physical activity (150-minutes per week), couple with a 5-10% reduction in body weight, also produced a 58% reduction in diabetes and cardiovascular risk factors, whilst pharmacology intervention using metformin produced 31% reduction in patients with high risk of developing type 2 diabetes (Joshi, 2008).

Obesity has become a burden on the health care cost; reduce quality of life and increased prevalence of the disease. The Improvement of socioeconomic status and the adoption of more sedentary lifestyle as well as unhealthy dietary habit showed that impaired glucose tolerance and obesity is now leading public health concern even among the rural communities. Obesity is most linked to socio-cultural and behavioral factors, including eating pattern, as well as the lack of awareness or knowledge on the associated health risk (Mohamud, 2011).

2.7 Prevalence of IGT, IFG, Diabetes mellitus and contributing factors

The prevalence of impaired glucose tolerance (IGT) and impaired fasting glucose (IFG) as well as undiagnosed diabetes is in the increase with epidemic proportion; not only in South Africa, but also elsewhere in the world. The study conducted in Bengo province of Angola, Evaristo-Neto et al (2010) reported that out of 421 subjects using the 2-hours 75-g oral glucose load, the prevalence of IGT and undiagnosed type 2 diabetes was 8.1% and 2.8% respectively. In this study, the random sample of 85 patients 30 to 65 years with 72% of female patients and 28% of male patients. By gender the prevalence of IGT, IFG and undiagnosed type 2 diabetes differ significantly between female patients (34% and 25%) and male patients (9.45 and 6.0%) because the high participation rate among female patients. Omar et al (1985) informed that this could have been due to fact that the study subject was skewed toward a predominantly female population. Similarly, a study by Evaristo-Neto et al showed that the participation rate was 30% for males and 70% for females, which was similar in this study. The prevalence of IGT among females was almost twice that found in males (9.1% vs. 5.6%), which was almost same for undiagnosed type 2 diabetes (3.2% for males and 2.7% for females), which was also similar to this study. Mutebi et al (2012) reported that out of 320 patients, the prevalence of IGT and undiagnosed type 2 diabetes was 50% and 24% which is extremely high due to high prevalence of hypertension, like Omar et al (1985) who show that the more the higher level blood pressure the higher the prevalence of IGT

Obesity is a significant risk factor in the rising prevalence of IGT, IFG and undiagnosed type 2 diabetes worldwide (WHO, 2010). The study showed that in both female and male patients, the prevalent rate of obesity was 25%, 41%, 18%, and 16%; for overweight; obesity grade I; obesity grade II obesity grade III respectively. In addition to this, the study also shows that poor diet, family history of hypertension, family history of diabetes, alcohol consumption, smoking, physical inactivity and hypertension were significant associated with the rise in prevalence of IGT, IFG and undiagnosed diabetes. Furthermore the waist circumference (WC) and the waist-to-hip ratio (WHR) were predictive risk factors of developing IGT, IFG, or DM among female patients (WC = 80-88cm as increases risk, WC \geq 88cm as higher risk) and (WHR = 0.81-0.85 and WHR $>$ 0.85; as predictive risk). This was different compared to male patients (WC = 94-102, as increased risk \geq 102 cm as higher risk) and (WHR = 0.96-1.0 and WHR $>$ 1.0 as a predictive risk).

This was similar in a study by Elbagir and Colleagues (1998), in their study of 724 subjects from a community of high diabetes prevalence in Sudan, showing a strong association between family history of diabetes and IGT. In the Teheran Lipid study, Hadaegh et al (2008) indicated that the high prevalence of

IGT, IFG and undiagnosed type 2 diabetes was associated with higher BMI, waist circumference, higher blood pressure and dislipidaemia. Dunstan et al (2002) also indicated that the prevalence in Australia was lower compared to developing nation and high compared to European nations. The high prevalence was due to changes in age profile and obesity.

A study conducted in Nigeria showed that prevalence of IGT was due to challenges faced by under-resourced primary care in screening for IGT among adults Nigerians (Iloh et al, 2013). In the USA, the prevalence of undiagnosed type 2 diabetes and impaired glucose tolerance was high due to a strong association with anthropometric risks, age, race/ethnicity, positive family history of diabetes, and hypertension (Heikes et al., 2008). In the United Kingdom (UK), the prevalence of IGT and undiagnosed type 2 diabetes was on the rise due to barriers to primary prevention of type 2 diabetes in black and minority ethnic groups, (Johnson et al., 2011). In India, the high prevalence was strongly associated with family history of diabetes, hypertension, overweight, obesity, large waist circumference, abdominal obesity and the nature of the work such as predominantly standing (Kumar et al., 2013). Similarly as indicated by Raghupathya et al (2010) that the association was due to a family history of diabetes, high BMI and waist/hip ratio, more household possessions, higher level of education, higher alcohol intake, and less physical activity. Insulin resistance was positively associated with lifestyle factors. Pyykkonen et al., (2010) reported that In Western Finland, the prevalence of undiagnosed diabetes, IGT and the metabolic syndrome was significantly on the increase among participants who experienced extremely stressful life event such as finance-related issues including ongoing and severe financial strain, threat of unemployment, or personal bankruptcy. It was also due to work-related issues such as trouble with coworkers or beginning of new job and the health-related domain such as concern over own or a child ability to cope with stress. In addition to extreme stress it was also due to housing-related issues such as loss of home, change of residence or difficulties in housing

In Cape Town, South Africa, the prevalence of undiagnosed diabetes was on the increase among wealthier persons, while IGT was more prevalent among older persons with very low levels of education, pensioners and these with poor housing living in shacks (Peer et al., 2012). In a similar study, by Ogunbanjo (2013) and Makinga (2013) it was shown that the prevalence of IGT, IFG or undiagnosed diabetes was extremely high due to the epidemic of obesity in South Africa and with a disparity on gender. The 2003 Demographic and Health Survey showed that 30% of South Africans are overweight or obese (Amod et al., 2012). Regarding gender, an observational study shown that 56% of South African women compared to 29% of

men were overweight or obese. The physical activity level of adults in SA is less than one-third. About 46% of all SA was reported to be physically inactive, resulting in weight gain and an increase in BMI (Van Zyl et al., 2010). Similarly, study by Van der Merwe (2004) informed that the greatest population attributable risk of impaired glucose tolerance or undiagnosed type 2 diabetes, occurs in SA people with a BMI of ≥ 25 kg/m² - 30 kg/m²; a waist circumference > 102 cm in men and > 88 cm in women, age > 40 years, African and Asian ethnicity, and having a sedentary lifestyle and stressful life conditions.

In 2011, the conservative South African study, estimated that 6.5% of adults aged 20-70 years have diabetes. According to the IDF (2013), the current national prevalence of IGT in 2013 in SA, is estimated at 8.3%. The link between urbanisation, unhealthy eating and rising levels of obesity are important contributors to the rising prevalence. In addition, the insidious and initially asymptomatic nature of the disease results in patients not seeking early medical attention until complications become apparent (Amod et al., 2012). In the Free State province of South Africa, a study by Groenewald (2009) showed that the prevalence of diabetes and IFG in adults patients was 7.6% and 6.3% respectively, however; of all participants, 62.5% were known to be diabetic; among which 37.5% were discovered during the survey. The Participants ages varied between 51 and 60 years. The study also showed that 23% of women were overweight and 41.6% were obese, compared to 14.6% and 7.5% of men respectively. The risk of having IGT, IFG or diabetes was also significantly higher in men and women ≥ 40 years with waist circumferences above the cut-off point value. The same tendency was observed in obese men with low activity and women with waist-to-hip ratio ≥ 0.85 (Groenewald et al., 2009).

A study conducted in Ga-Mothapo village, Capricorn District of Limpopo province indicated that the prevalence of overweight, obesity, high blood pressure and hyperglycaemia was very high, namely 30.6%, 23.6%, 27% and 11.8% respectively. The prevalence was higher among females than males and there was significant association with anthropometric profile, blood pressure and hyperglycaemia (Sengwayo et al., 2013). In the Ubombo district of rural northern KwaZulu-Natal, it was shown that the prevalence of undiagnosed diabetes, IGT and IFG were 4.6%, 6.4%, and 1.6% respectively, using the ADA and the WHO diagnostic criteria. With regard to diabetes, 84.8% were discovered during the survey. The risk factor analysis indicated that there were family history of diabetes, history of alcohol ingestion, larger waist circumference, total serum cholesterol, and serum triglycerides. The rural community was entering an epidemic of glucose intolerance, significantly associated with potentially modifiable risk factors (Motala et al., 2008). A study conducted in Springfontein and Trompsburg investigating the contributing factors in the

development of IFG showed that 37.5% of people were undiagnosed and were discovered during the screening. The prevalence of DM was 7.6% (5.2% in men and 8.6% in women) and that of IFG was 6.3% (4.5% in men and 7.1% in women). Waist circumference, waist-to-hip ratio, and physical inactivity in men \geq 40 years were significant risk factors for having IFG or DM (Groenewald et al., 2009).

The coloured population had been reported to show the second-highest prevalence of diabetes. A study was conducted in Bellville, Cape Town, aiming to determine the prevalence of diabetes and metabolic syndrome; the results indicated that the prevalence of diabetes was 28.2% and that for undiagnosed diabetes was 18.1%. The prevalence of pre-diabetes states like IGT and IFG was 15.3% and 4.4% respectively and the combined IFG/IGT was 4.3%. In this study, age (>40 years old), waist circumference, and a family history of diabetes were associated with both diabetes and IGT/IFG. In addition to this, metabolic syndrome was more prevalent in females, and central obesity was the most common abnormal criterion, followed by raised blood pressure, reduced HDL, hyperglycaemia and raised triglycerides. (Erasmus et al, 2012).

2.8 Specificity and sensitivity of the test

The American Diabetes Association prefers to use the fasting plasma glucose level for screening, because it is faster, more acceptable to patients, and less expensive than other screening test. The fasting plasma glucose level also is more reproducible than 75-g glucose tolerance test and varies less between patients. However, the 75-g oral glucose tolerance test is more sensitive (Shobha, 2004). A study by Heikes (2008) also informed that the 75-g plasma glucose was still the best test to confirm the diagnostic. That the sensitivity of the 75-g plasma glucose is greater than the sensitivity of FPG and Shaw (1999) indicated that screening by the criterion of fasting plasma glucose alone would identify fewer people who would subsequently progress to type 2 diabetes than the oral glucose tolerance test would

Chapter 3: Methodology

3.1 Study design

The design was a cross-sectional study. This is a study that collects data on subjects at one point in time (Brink, 2008). It is also a status of individual with respect to presence and absence of both exposure and disease assessed at one point in time. Cross-sectional study allows for the determination of the association between variables, but does not allow for assessment of temporal relationship between variables (Toronto notes, 2010).

3.2 Study setting

The Northern Cape is one of the nine provinces of South Africa with capital city of Kimberley. It is covering an area of 372,889 Km² and composed of five districts: Namakwa, Pixley ka Seme, Siyanda, Frances Baard, and John Taolo Gaetsewe. There are at least 6 different languages spoken: Sotho, English, Xhosa, Tswana, and Afrikaans. Afrikaans is the most spoken language of the region. The total population is estimated at more than 1,162,900 (Stat. 2013). The population groups are composed of Black African as a majority, followed by Coloured, Whites, and Indians. The Northern Cape most economic activities including diamond mine, agriculture, and winery (Parkington, 2008; Alexander, 2002; Morris, 2004; Stat SA, 2013). The burdens of diseases in the province are generally communicable and non-communicable diseases, maternal and perinatal problem, nutritional and injuries. The most common disease is HIV and AIDS. The study was carried out at the outpatient department of Prof ZK Matthews Hospital (PZKMH). This is a 50-bed, level-one district hospital. In the community, there are clinics surrounding PZKMH which include five fixed clinics, two mobile clinics, and also some satellite clinics; which are Primary Health Care level referring patients to PZKMH. The hospital and clinics are located in the Barkley West community. Cardiovascular, respiratory, diabetes mellitus, and nutritional are health conditions encountered as in hospital diseases, in addition to HIV/AIDS related conditions; such as TB genito-urinary, injuries, infectious diseases, and malignant-neoplasms. In this study the focus is more on impaired glucose tolerance, impaired fasting glucose, and undiagnosed diabetes mellitus due high morbidity, mortality, disability and others damages to patients. In the hospital more gangrene are seen, loss of vision, stroke, cardiovascular complications such myocardial infarction, renal failure, and peripheral venal diseases.

3.3 Study population

All middle-aged adult patients having the risk of developing impaired glucose tolerance, impaired fasting glucose or undiagnosed diabetes who are attendees of the outpatient department of the Prof ZK Matthews Hospital formed the study population. A total of 85 patients formed the study sample. The anthropometric measurement was used to determine the risk profile of each patient. These patients presented generally with monopathology or poly pathology such as blurred vision with undiagnosed diabetes, obesity with impaired glucose tolerance, angina or silent myocardial infarction with undiagnosed diabetes. Many of these patients were having the high risk of developing further complications. They underwent screening test as per both the American Diabetes Association criteria and the World Health Organisation; after subjects have been determined and selected in the population study.

3.4 Study sample

To calculate the sample size, a calculator tool was used from the survey system available in the internet. The confidence interval (margin of error) used to estimate the number of completed survey was 10%, the study power was 50%, and the confidence level was determined at 95%. The study population was 700 patients at risk of abnormal glucose tolerance. All these elements (700, 10%, 50% and the 95%) were run into the software tool and the output shows that the sample size needed was 85. A simple random sample method was used to calculate the sample size as shown in the formula below.

The sample size formula used in the simple size calculator tool was:

$$SS = \frac{Z^2 * (p) * (1-p)}{C^2}$$

Where:

Z = Z value (95% confidence level)

P = percentage picking a choice, expressed as decimal (10%)

C = confidence interval, expressed as decimal

3.5 Selection for screening

About 1374 adult male and female patients were initially registered to be enrolled in the study. During the selection process the following were excluded: 17 females were pregnant at different gestational ages, 147 patients were below the age of 30 years and 76 were above 65 years. During history taking, 134 patients were reactive on ARV treatments, 21 females were breastfeeding, 13 were acutely ill, and 170 had diabetes on treatment. A routine verification on registered patients was carried out and it was discovered that 43 patients did not show up for further selection. 53 patients came from different areas and were not permanent residents in the community of Barkley West.

Out of 1374, about 674 patients (49.0%) did not meet the inclusion criteria, and were therefore excluded from the study and only 700 patients (51%) met the inclusion criteria and they underwent the random capillary finger puncture to test the random blood glucose concentration. Patients with a capillary blood glucose concentration ≥ 5.5 mmol/l were considered positive for screening. Thereafter they were submitted to a 2-hour 75-g glucose load oral glucose tolerance test and were also submitted to a fasting plasma glucose test following an overnight 12-hours fasting period. The number of people needed for fasting and OGTT were 85 after applying a simple random sample method. $N = 85$ is a sample size calculated using a 95% confidence level, study power of 50% and confidence interval of 10%.

3.6 Inclusion criteria

Patients with a BMI ≥ 25 kg/m²

Patients with levels of plasma glucose ≥ 5.5 mmol/l

Patients aged between 30 and 65 (inclusive)

Patients who signed the informed consent form

3.7 Exclusion criteria

Patients living with diabetes mellitus type 1 or type 2

Patients who are visiting, immigrant, or non-residents of the Barkley West community

Patients with acute illness

Patients with mental illness

Patients with pregnancy: antepartum, post-partum, or breastfeeding

Patient living with HIV/AIDS

Patients under 30 years or above 65 years

Patients who refused to sign the informed consent form

3.8 Data collection

The data for this study was collected from the 15th of December 2012 to the 20th of February 2013. A questionnaire was used to collect the data. The researcher trained the research assistant who is a qualified dietician and also proficient in the local language (Afrikaans) to administer the questionnaire. The questionnaire was designed by the researcher with the assistance of the dietician. The interviewer administered the questionnaire, and was pretested with 10 middle-aged adults at risk of abnormal glucose levels, who were not included in the study. This was used as the sole foundation of data collection for this study. The majority of the questionnaires were administered in Afrikaans by the research assistant. Patients were allowed to answer the questionnaire in the language of their choice, i.e. the language they understood better: English or Afrikaans. The questionnaire was divided into the following categories: socio-demographic category, blood pressure measurement, anthropometric measurements, and blood test by the capillary and laboratory methods.

3.9 Socio-demographic characteristics

All the questions were completed by each patient with the help of the research assistant and the researcher. The information collected included age, gender, level of education, employment status, monthly income, and marital status.

3.10 Anthropometric measurements

For anthropometric measurements, patients dressed in light clothing and with bare feet stood on a calibrated stadiometer (SECA scale with height rod graduated in centimeters) to obtain the weight and the height. The height was measured to the nearest 0.5 cm and the weight was recorded to the nearest 100 g. The scale was adjusted every time for every patient to minimise errors. The body mass index (BMI) was calculated by the formula: weight in kilograms divided by height in meters squared. Patients were classified according to the Body Mass Index information obtained from the BMI calculations.

3.10.1 Table I: Classification of Body Mass Index (Van der Merwe, 2004)

| BMI | < 18.5 kg/m ² | 18.5 – 24.9 kg /m ² | 25 – 29.9 kg / m ² | >30 kg / m ² |
|----------------|--------------------------|--------------------------------|-------------------------------|-------------------------|
| Classification | Underweight | Normal | Overweight | Obese |

The waist circumference (WC) was estimated for every patient as a measure of abdominal obesity. This was measured at the approximate point between the lower margin of the last palpable rib cage and the top of the iliac crest using a flexible plastic tape. Hip circumference was measured to the nearest 1 cm at the level of the maximum circumference around the buttocks posteriorly and at the symphysis pubic anteriorly.

3.10.2 Table II: WHO Classification of risk factors of IGT, IFG, or diabetes (Van der Merwe, 2004)

| Status | Waist circumference (cm) | BMI (kg/m ²) | Classification of obesity |
|-------------------|----------------------------------|--------------------------|----------------------------|
| Healthy or normal | Males < 94 and Females < 80 | 18.5 – 24.9 | Normal |
| Increasing risks | Males 94 –102 and Females. 80-88 | 25 – 29,9 | Overweight to obese |
| High risks | Males > 102 and Females > 88 | >30 | Obesity class I, II or III |

3.11 Blood pressure measurements

History of hypertension was considered positive when patients were diagnosed to have hypertension. Blood pressure (BP) was measured in sitting position on the right arm, using a calibrated digital automatic BP monitor, the Visocor® OM40 with an appropriately sized cuff, after the patient had been seated for five minutes. Three blood pressure measurements were taken at 5 minute intervals: first measurement by a professional nurse, the second measurement by the research assistant, and the third measurement by the researcher. The average of the second and the third BP measurements was used in the analysis. Hypertension is defined as systolic BP of ≥ 140 mmHg or diastolic ≥ 90 mmHg.

3.12 Blood glucose measurements

Capillary blood from a finger prick was analysed (first phase of the study) to measure random blood glucose concentration by glucose oxidase method, using a portable electronic blood glucose monitor (Accu Check Active®) with commercially available strips. Patients with random capillary glucose concentration ≥ 5.5 mmol/l were positive for screening and were immediately submitted to a 75-g oral glucose tolerance test (OGTT). Two-hour later, capillary and plasma glucose were measured (second phase of the study). Fasting plasma glucose and fasting capillary glycaemia was measured following an overnight fasting of 8 to 10 hours (third phase of the study). All blood samples drawn were sent to the laboratory within 3 hours for analysis.

3.12.1. Table III: Screening test by ADA and WHO diagnostic criteria (Joshi, 2008)

| Diagnostic criteria | IGT | IFG | DM |
|---------------------|-------------------|------------------|--------------------|
| WHO | 7.8 – 11.0 mmol/l | 6.1 – 6.9 mmol/l | ≥ 11.1 mmol/l |
| ADA | < 7 mmol/l | 5.6 – 6.9 mmol/l | ≥ 7 mmol/l |

3.13 Data analysis

Data was captured on an Excel spreadsheet and exposed to a Statistics Package of Social Sciences (SPSS) 21.0 statistical analysis software® and data analysis was done with the help of a statistician. Simple descriptive analysis was performed. The variables used in the analysis were: age, education level, employment status, and BMI. Descriptive statistics of the anthropometric variables were weight, height, BMI, waist circumference and risk-factors were predicted using waist/hip ratio. The Fisher Exact Test was used to compare the categorical measurements. Statistical significance was set at $p = 0.05$.

3.14 Reliability of the study

To ensure validity a pilot study was conducted in a different area to test the questionnaire and the result served as a sole instrument for data collection. The researcher used a validated existing questionnaire from previous studies modified and adapted for this study. Also the researcher made use of SEMDSA, WHO, ADA, and IDF guidelines to formulate the questionnaire. In addition, the researcher was also assisted by the dietician. Questionnaire were administered first by the research assistant and secondly by both the researcher and the research assistant to every participant, to ensure reproducibility of their responses.

3.15 Validity of the study

Validity was ensured by testing four times each patient level of glucose concentration. This was done twice by capillary finger puncture (randomly) and fasting, and also blood was drawn twice to test the plasma glucose level 2-hour post-load 75-g glucose (WHO criteria) and fasting plasma glucose after starving overnight for 8-10 hours (ADA criteria). Patients were weighed with bare feet in light clothing. The scale was standardised before the study and was also adjusted or calibrated each time after each patient was measured. The blood pressure was measured three times for each patient and the average of the second and the third was considered to be the blood pressure measurement.

3.16 Bias

Bias cannot always be eliminated and must be recognised. The following kinds of bias might have occurred in this study:

3.16.1 Selection bias

This was minimised by randomly selecting all adult patients at risk of impaired glucose tolerance, impaired fasting glucose, and undiagnosed type 2 diabetes attending the outpatient department at the Prof ZK Matthews Hospital and who met the inclusion criteria. It was not possible to eliminate selection bias completely as an error may be introduced by poor anthropometric measurement technique or by selecting patients already having diabetes mellitus.

3.16.2 Bias of data presentation or interpretation

Bias introduced via technical errors from poor techniques, incomplete data and errors arising from inference which may stem from the researcher failure to consider every interpretation consistent with the facts. This was minimised by requesting the assistance of a statistician.

3.16.3 Measurement bias

This type of bias occurs if the instrument or when the measurement tool is not calibrated. The weighing scale was calibrated each day and before weighing the patients and each time again after weighing each patient. Some patients may also have been weighed with shoes on and in heavy clothing.

3.16.4 Sampling bias

This bias may be introduced when the study population does not have an equal chance of selection in the study. To minimise this bias the researcher used the probability sampling method with random numbers to give equal chance of selection.

3.17 Clinical implication

The results of this study will be utilised at primary health care level as evidence-based-medicine to improve the clinical practice. The results will be published in a scientific journal and may also be presented at a scientific conference. The study should contribute to the body knowledge available to health professionals.

3.18 Ethical considerations

Ethical approval of the study was obtained from the School of Health Science Senior Degree Committee of the University of Limpopo, Turfloop Campus, and from the Medunsa Research and Ethic Committee (MREC). The Clearance Certificate Number of the University of Limpopo, Medunsa Campus is MRECHS/240/2012: PG, and the Northern Cape Department of Health, NC PHREC reference number is NC2012/007. Permission was also obtained from Prof ZK Matthews Hospital. Before commencement of the study, the researcher obtained a written informed consent from each patient to participate in the study, after the aim and objectives of the study were explained. Patients were informed that their medical care at the hospital would be unaffected if they declined participation or withdrew from the study, and without penalty or being treated negatively. Patients had freedom of choice of local language or English. Anonymity and confidentiality of the patient were maintained throughout the study by using only numbers on the questionnaires. Data was analysed as group data.

Chapter 4: Results

4.1 Introduction

The following socio-demographic data were considered by the researcher: age, gender, marital status, employment status, level of education, and total monthly income. The anthropometric data such as weight, height, waist circumference, and hip circumference were used to determine the patient risk profile and determine a prediction of the patient risk of developing the disease. Weight and height helped to calculate and classified patients BMI accordingly, namely as overweight, obese, or extremely obese. Screening data for impaired glucose tolerance; impaired fasting glucose and undiagnosed type 2 diabetes was computed and a descriptive analysis was done.

4.2 Socio-demographic characteristics

4.2.1 Age group

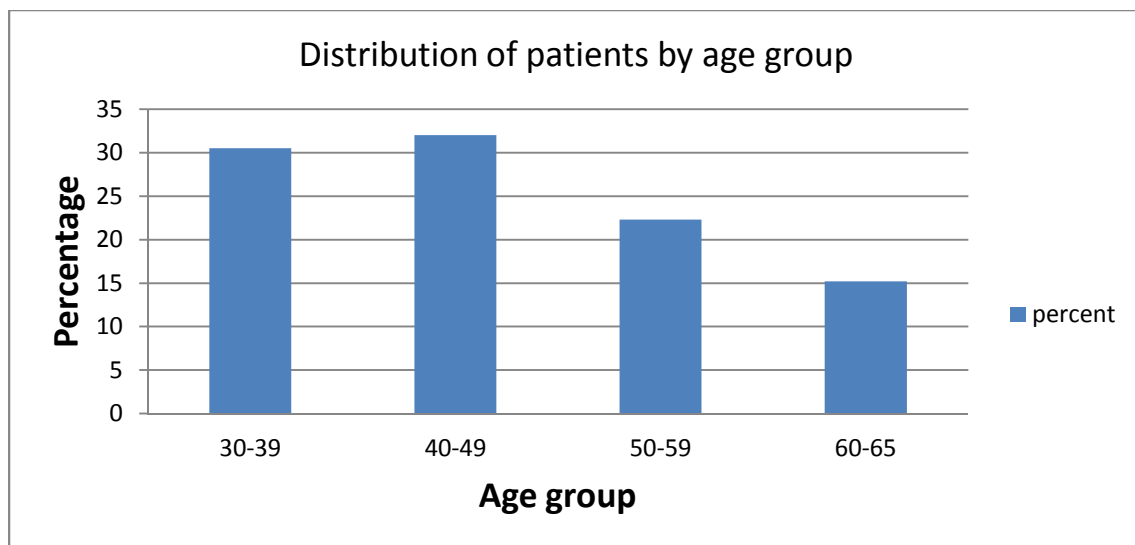


Figure I: Distribution of patients by age group

The dominant age group was that of 40-49 years old (32%), followed by the age group 30-39 years old (30.5%). The minority population was that of 50-59 years old (22.3%), followed by the 60-65 years old (15.2%), that is, the elderly population of intermediate hyperglycaemia.

4.2.2 Gender

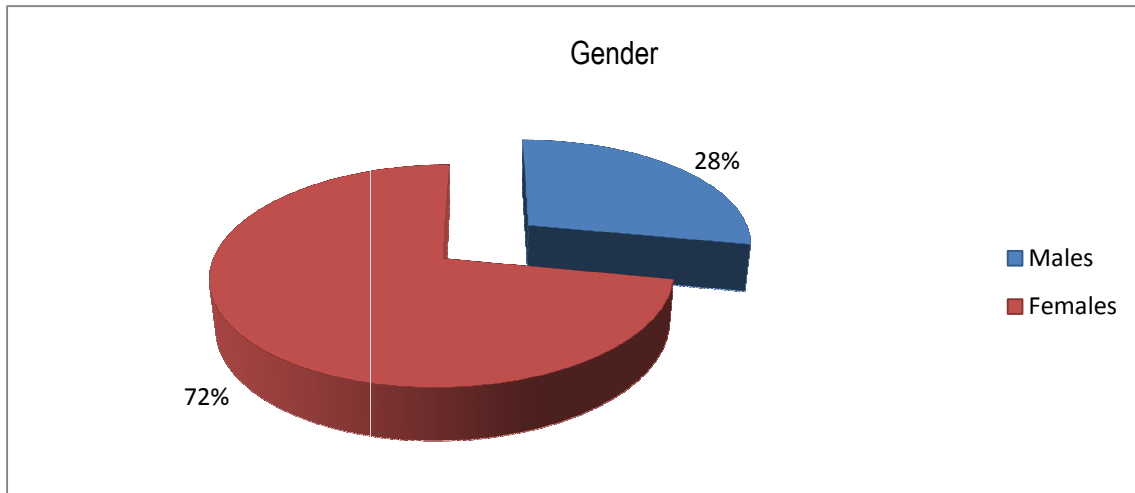


Figure II: Distribution of patients by gender

This was a predominantly female population. Seventy-two percent (72%) were female and only 28% were male. This gave a female-to-male ratio of 3:1.

4.2.3 Marital status

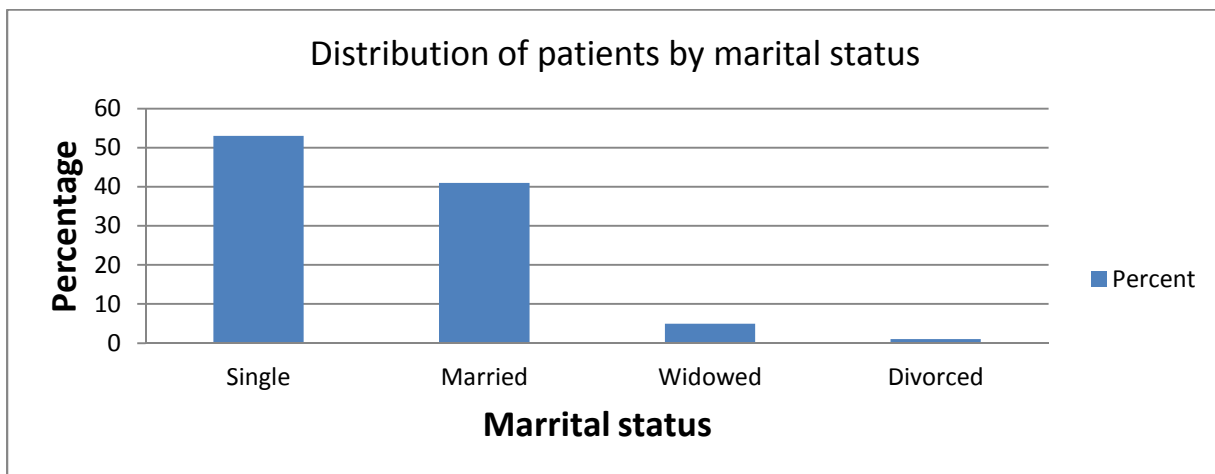


Figure III: Distribution of patients by marital status

The number of patients who were single was high (53%), compared to those who were married (41%). Very few patients were widowed (5%), followed by those who were divorced (1%).

4.2.4 Employment status

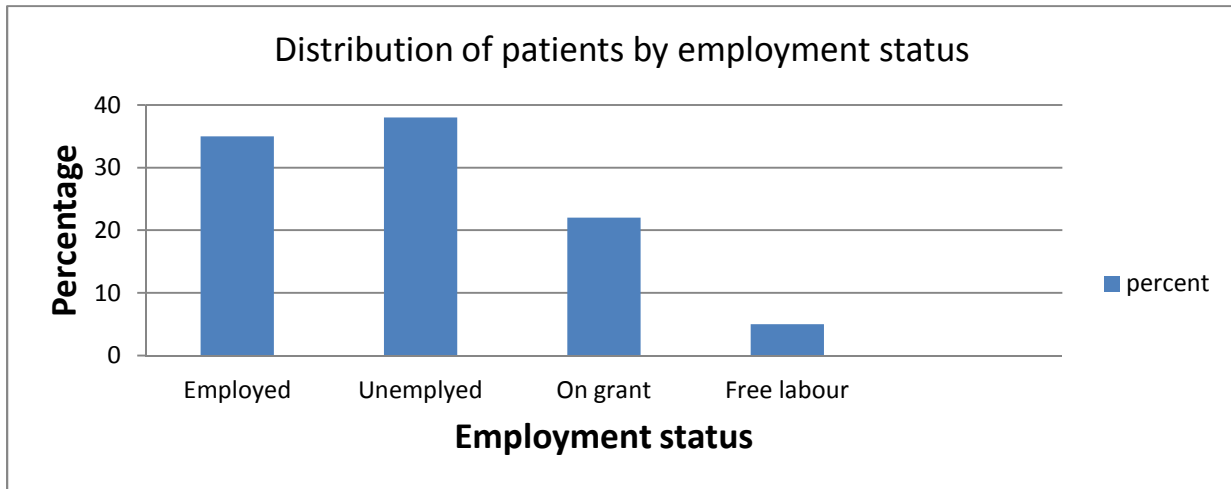


Figure IV: Distribution of patients by unemployment status

The population of patients that was unemployed was higher (38%) than those who were employed (35%). Less than a quarter of the patients (22%) were on grants and this was followed by 5% of the patients who were either self-employed or had a free labour on part-time or full-time basis.

4.2.5 Education

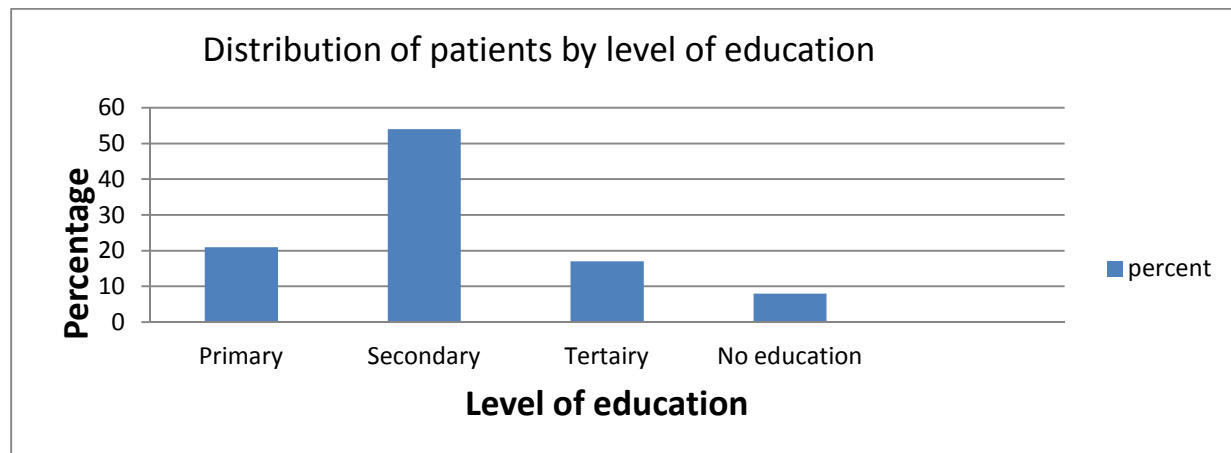


Figure V: Distribution of patients by level of education

The number of patients who had a secondary school education was higher (54%), followed by those who had primary school education (21%). Only 17% of the patients had tertiary education and 8% of the patients did not have any formal education.

4.2.6 Total monthly family income in Rand (R)

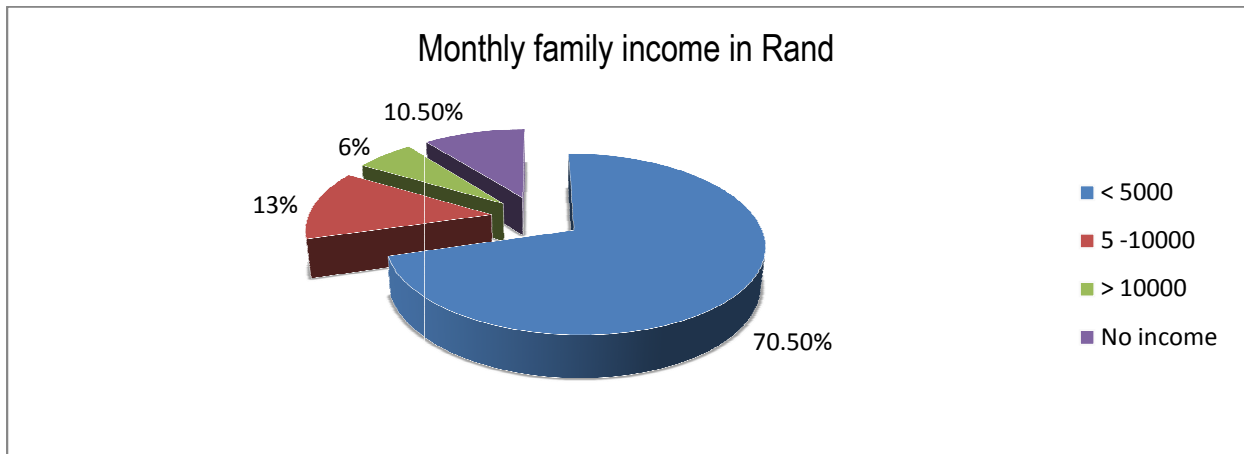


Figure VI: Distribution of patients by monthly income

The number of patients with monthly income less than R5000 was high (70.5%), followed by those (13%) who had between R5000 and R10000. Only few patients (6%) had a monthly income higher than R10 000. The remaining patients (10.5%) had no monthly income.

4.3 Anthropometric profile

4.3.1 Body Mass Index (BMI)

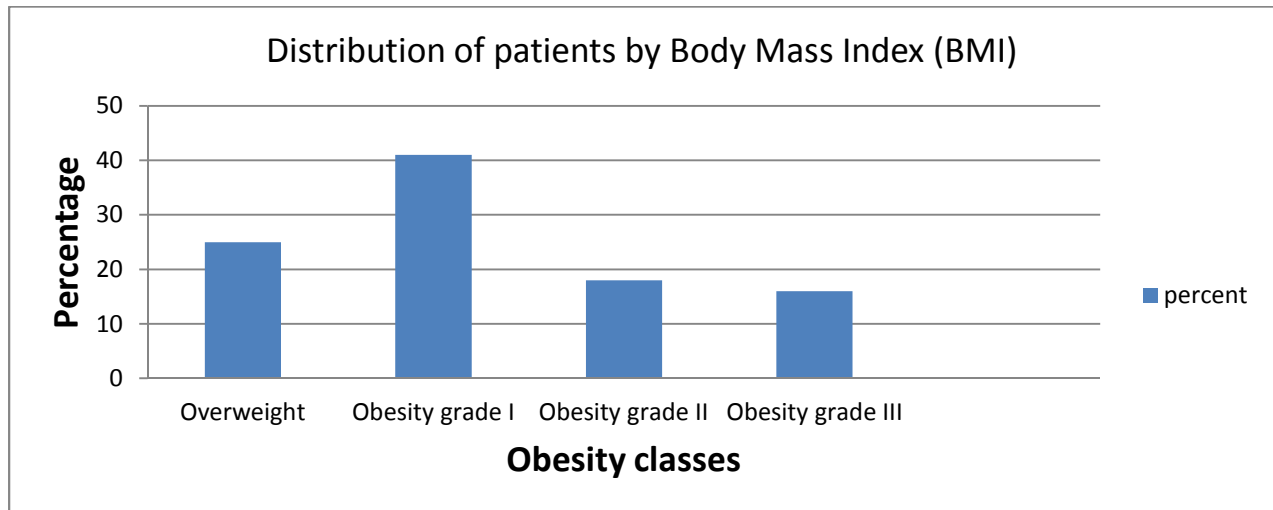


Figure VII: Distribution of patients by Body Mass Index

The figure shows that almost 75% of patients were obese, translated as BMI ≥ 30 kg/m²; and only 25% were overweight translated as BMI of 25-29.9 kg/m². The number of patients with obesity grade (I) were 41% (BMI of 30-34.9 kg/m²), followed by 18% with obesity grade (II) (BMI of 35-39.9 kg/m²) and 16% with obesity grade (III) (BMI ≥ 40 kg/m² or morbidly obese).

4.3.2 Obesity by age group

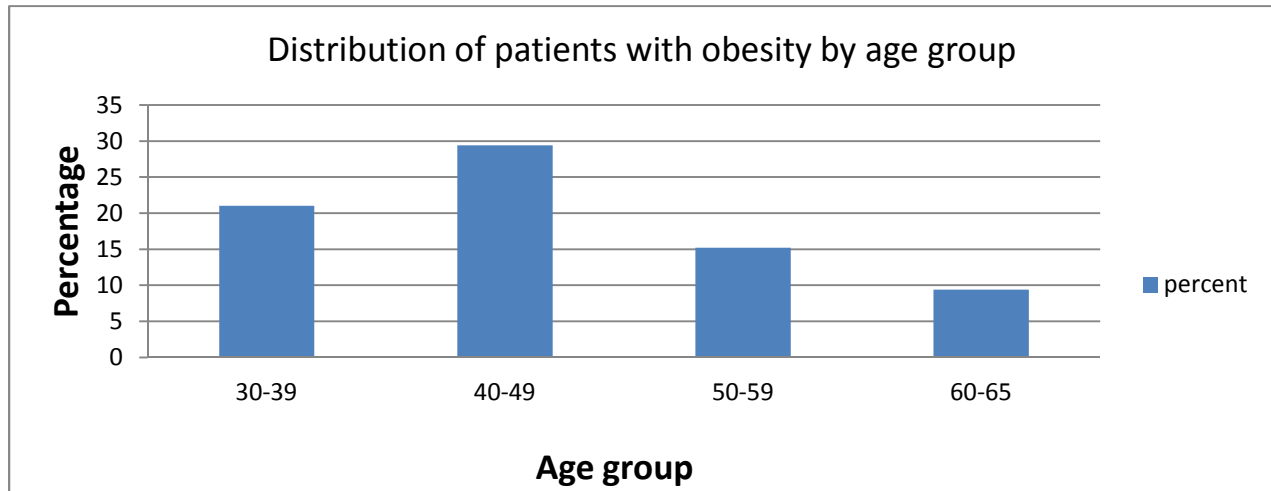


Figure VIII: Distribution of patients with obesity by age group

The prevalence of obesity was high (29.4%) among the 40-49 age group, followed by 21% in the 30-39 age group. The prevalence of obesity was lower (15.2%) in the 50-59 age group, followed by 9.4% in the 60-65 age group.

4.3.3 Overweight and obesity by gender

Table IV: Distribution of patients with obesity by gender

| Classification | | Normal (BMI < 25 kg/m ²) | Overweight (BMI ≥ 25 kg/m ²) | Percentage of overweight | Obese Grade I (BMI 30-34.9 kg/m ²) | Obese Grade II (BMI 35-39.9 kg/m ²) | Obese Grade III (BMI ≥ 40 kg/m ²) | Total | Percentage of obesity |
|------------------------|---------|---|---|-----------------------------|---|--|--|-------|--------------------------|
| No. of Patients | | 0 | 21 | 25% | 36 | 13 | 15 | 64 | 75% |
| Gender | Females | 0 | 15 | 18% | 22 | 10 | 14 | 46 | 54% |
| | Males | 0 | 6 | 7% | 14 | 3 | 1 | 18 | 21% |

The overall prevalence of overweight and obesity was 25% and 75% respectively. The frequency of obesity was high among females patients in all the categories grade I, grade II, and grade III. This was translated to 54% of obesity among the females and 21% of obesity among the males.

4.3.4 Waist-to-hip ratio: For male

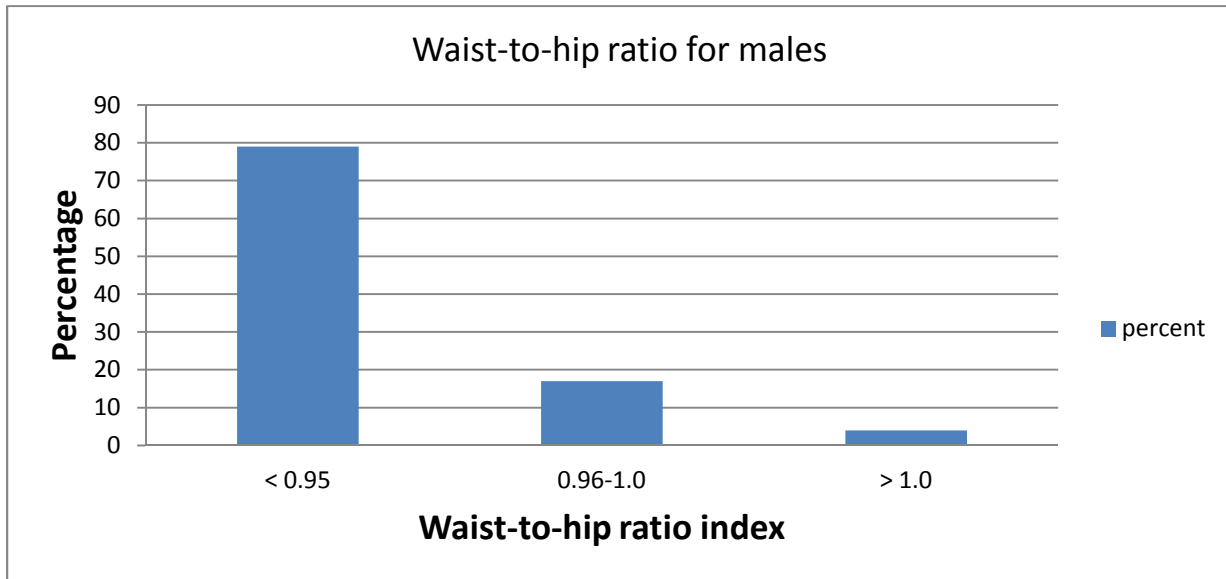


Figure IX: Distribution of male patients by waist-to-hip ratio

Nineteen male patients out of 24 (79%) had a waist-to-hip ratio < 0.95, followed by four patients (17%) who had a waist-to-hip ratio of 0.96-1.0, and only one patient (4%) who had a waist-to-hip ratio > 1.0.

4.3.5 Waist-to-hip ratio: For females

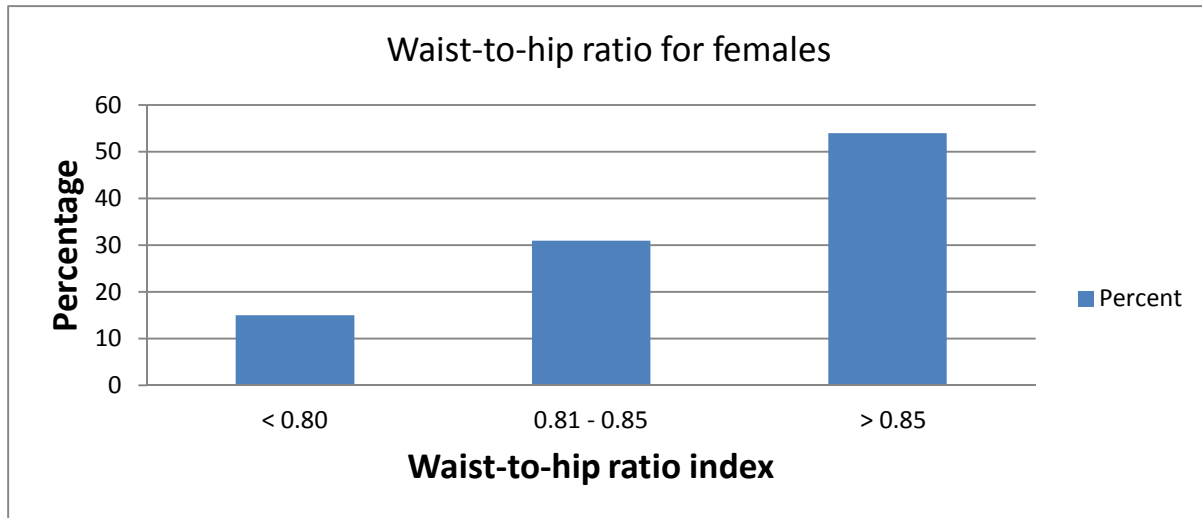


Figure X: Distribution of female patients by waist-to-hip ratio

The majority of female patients (54%) had a waist-to-hip ratio of > 0.85, followed by 31% female patients with a waist-to-hip ratio of 0.81 – 0.85 and only 15% of female patients had a waist-to-hip ratio < 0.80.

4.3.6 Anthropometric profile and the risk of developing IGT, IFG, or DM

Table V: Distribution of patients by anthropometric profile, gender and age group

| Anthropometric measurements | | Incr. risk: w/c: 80-88 cm | Higher risk: w/c: \geq 88 cm | Risk of dev. IGT, IFG or DM | w/h Ratio < 0.80 | w/h ratio 0.81-0.85 | w/h ratio > 0.85 | Predictive risk of dev. IGT, IFG, DM |
|-----------------------------|---------|---------------------------|--------------------------------|-----------------------------|-----------------------|---------------------|------------------|--|
| Total No./fem. pts | | 4 | 57 | 71.7% | 9 | 19 | 33 | 61.1% |
| Age group | 30 - 39 | 4 | 16 | 23.5% | 3 | 5 | 10 | 17.6% |
| | 40 - 49 | 0 | 20 | 23.5% | 2 | 4 | 6 | 11.7% |
| | 50 - 59 | 0 | 14 | 16.5% | 3 | 6 | 13 | 22.3% |
| | 60 - 65 | 0 | 7 | 8.2% | 1 | 4 | 4 | 9.5% |
| | | | | | | | | |
| Anthropometric measurement | | Inc. risk w/c: 94-102cm | Higher risk w/c \geq 102cm | Risk of dev., IGT,IFG or DM | w/h ratio \leq 0.95 | w/h ratio 0.96 -1.0 | w/h ratio > 1.0 | Predictive risk of dev. IGT, IFG or DM |
| Total No./ males pts | | 16 | 8 | 28.2% | 18 | 5 | 1 | 7% |
| Age group | 30 - 39 | 4 | 3 | 8.2% | 3 | 2 | 1 | 3.6% |
| | 40 - 49 | 3 | 4 | 8.2% | 6 | 0 | 0 | 0% |
| | 50 - 59 | 3 | 1 | 4.7% | 5 | 1 | 0 | 1.1% |
| | 60 - 65 | 6 | 0 | 7.1% | 4 | 2 | 0 | 2.3% |

Table V shows the anthropometric measurement of patients according to gender and age group. The age group 30-39 and 40- 49 has the higher increase risk of developing impaired glucose tolerance or diabetes with WC \geq 88 cm for females and WC \geq 102 cm. This particular age group shows 8.2% for male patients and 23.5% for female patients. The age group 50 – 59 and 60 – 65 had an increase risk of developing the disease [4.7% for 50 - 59 and 7.1% for 60 – 65] among male patients with a WC between 94-102 cm, while female patients had a higher risk of developing the disease in the same age group with WC \geq 88 cm [16.5% for 50 – 59 and 8.2% for 60 – 65]. The overall risk of developing IGT, IFG or diabetes was 8/85 (28.2%) for male patients and 57/85 (72%) for female patients.

The waist-to-hip ratio in this table shows that among female patients, the predictive risk of developing IGT, IFG or diabetes was higher 22.3% in the 50 -59 age group, following by 30 – 39 (17.6%) and lower (9.5%) in the 60 – 65 age groups. The 40 – 49 age group represented 11.7%. This means that more female patients had a WHR $>$ 0.85. The predictive risk of IGT, IFG or diabetes among male patients was not significant due to low rate of participation. There was only one male patient with the WHR $>$ 1.0 which represent 3.6% predictive risk in the 30 – 39 age group and 0%, 1.1%, and 2.3% in the 40 – 49, 50 – 59, and 60 – 65 age group respectively; had a WHR between 0.96 – 1.0. The overall predictive risk of developing IGT, IFG or diabetes was [33/85] (61.1%) for female patients and only [1/85] (7%).

4.4 Contributing risk factors

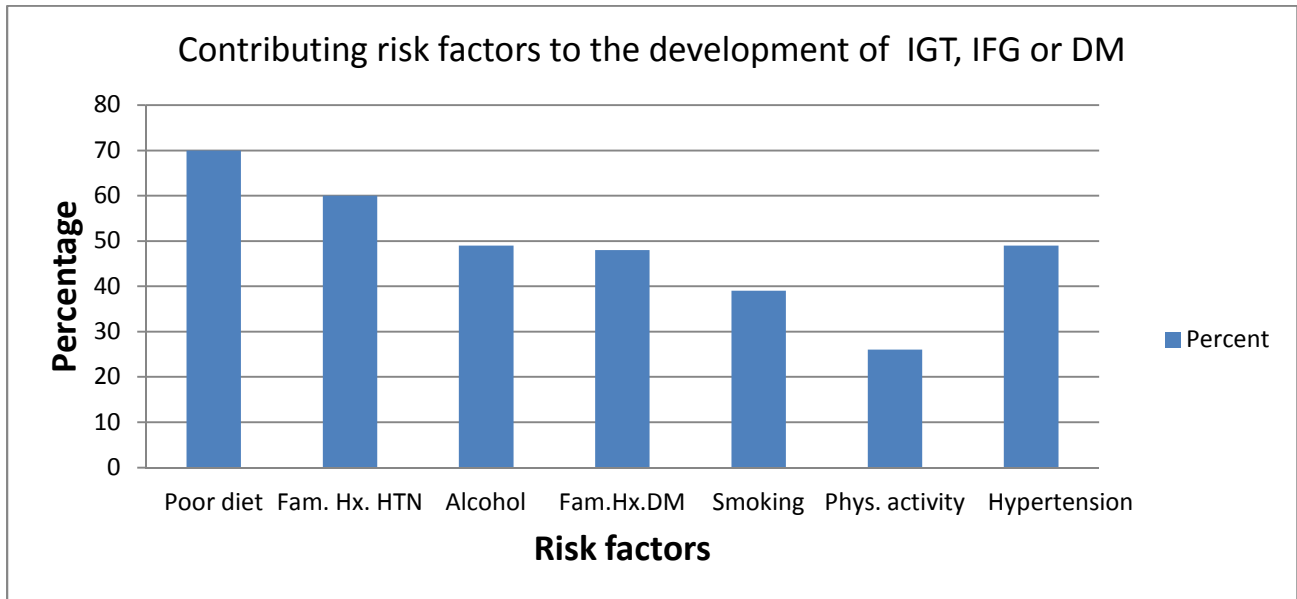


Figure XI: Distribution of patients by contributing risk factors

The majority of the patients (70%) had a history of poor diet, followed by those living with existing first-degree family history of hypertension (60%) and alcohol consumption (49%). There were also 48% of patients with the first-degree of family history of diabetes mellitus. Few patients (26%) were involved in physical activity and 39 % were involved in smoking habit, and also, 49% of patients in the study were having hypertension.

4.5 The prevalence of IGT and IFG

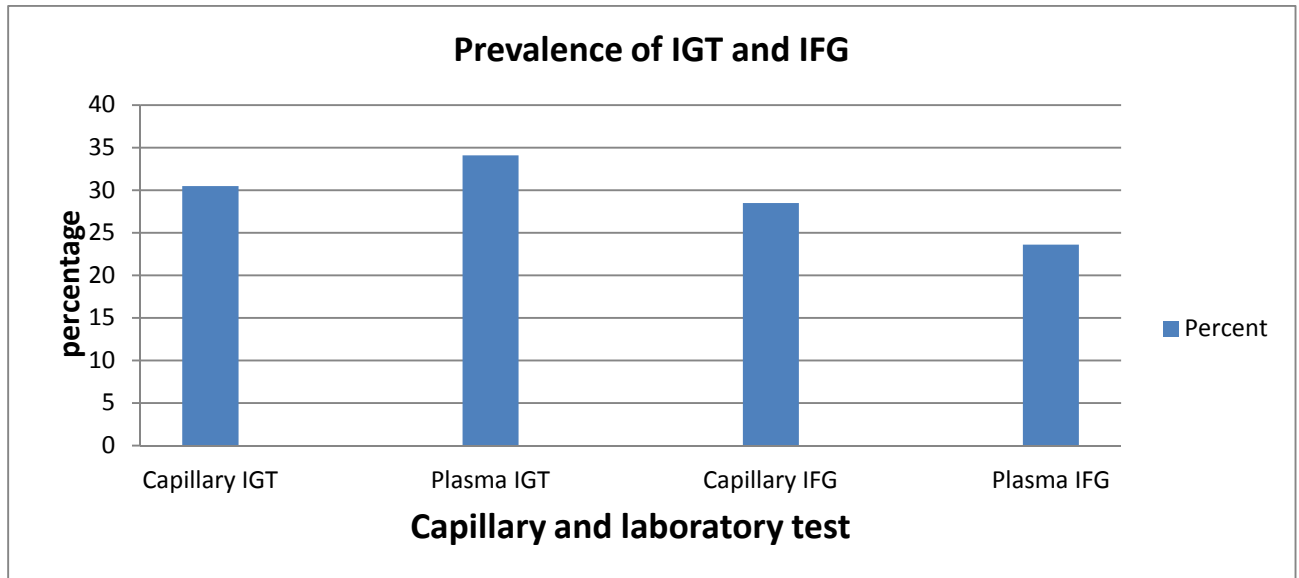


Figure XII: Prevalence of IGT and IFG (ADA and WHO criteria)

The overall prevalence of IGT and IFG by the laboratory method (random and fasting plasma glucose) was 34.1% and 23.6% respectively and that by the capillary method, the prevalence of IGT and IFG was 30.5% and 25.8% respectively.

4.5.1 Prevalence of IGT and IFG by gender: Female patients

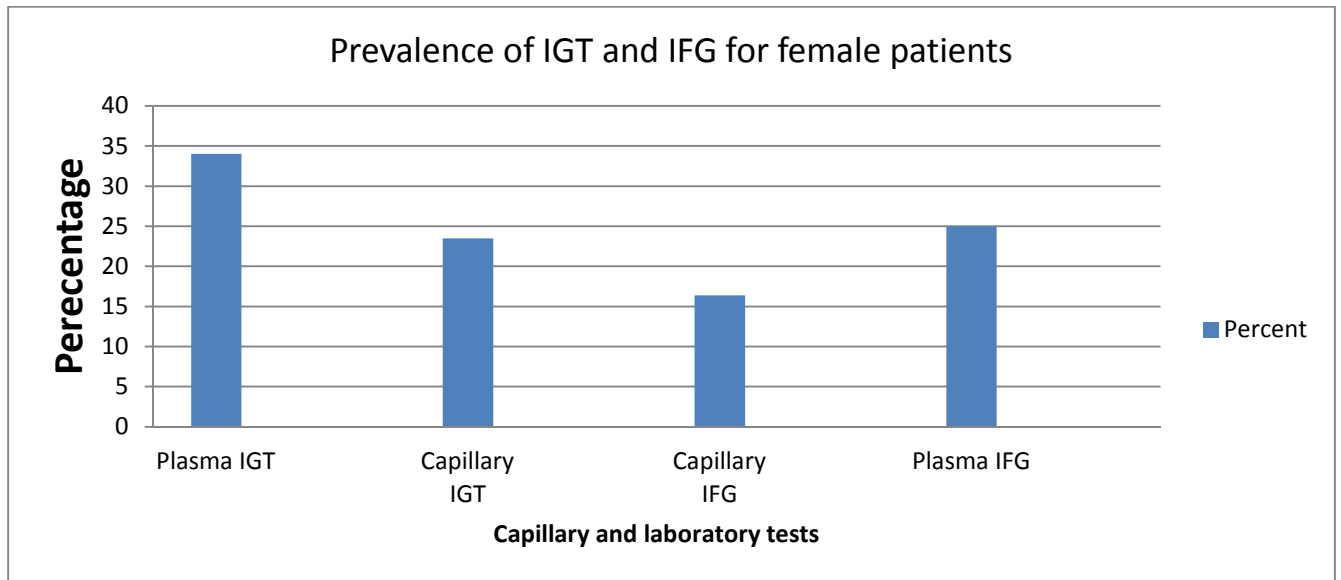


Figure XIII: Prevalence of IGT and IFG among female patients

The prevalence of IGT and IFG tested by the laboratory method (random and fasting plasma glucose) was 34% and 25% respectively, while for IGT and IFG tested by the capillary method, the prevalence was 23.5% and 16.4% respectively among female patients. IGT was higher than IFG by the laboratory method, while IGT was also higher than IFG by the capillary finger puncture method.

4.5.2 Prevalence of IGT and IFG by gender: Male patients

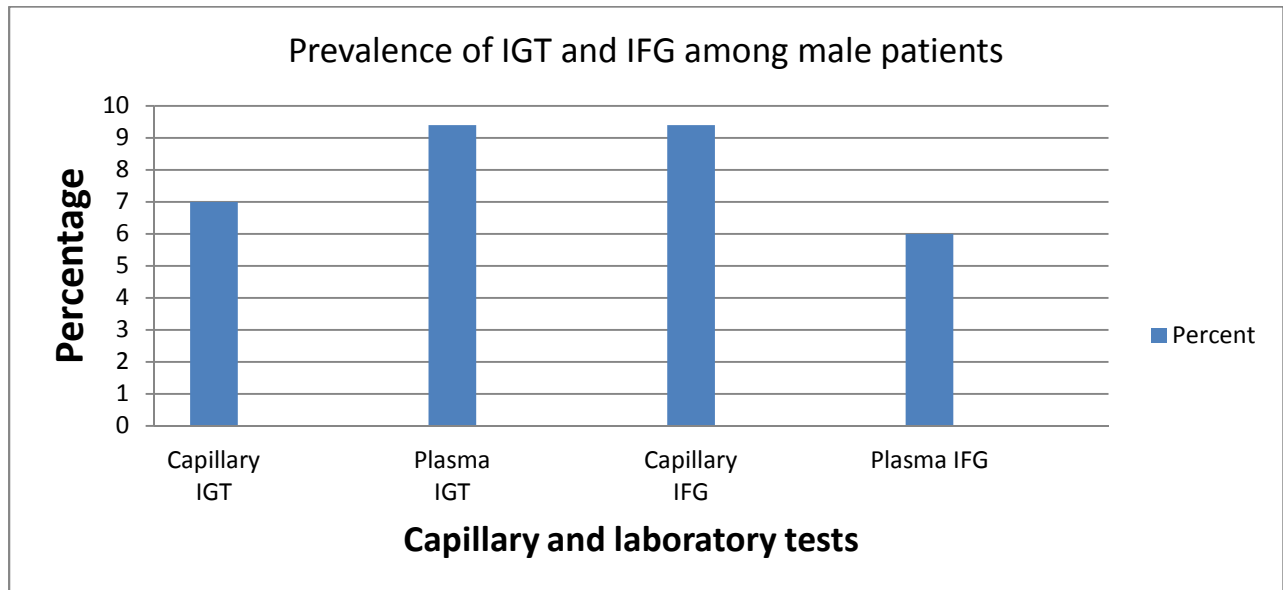


Figure XIV: Prevalence of IGT and IFG among male patients

The prevalence of IGT and IFG tested by the laboratory method (random and fasting plasma glucose) was 9.4% and 6.0% respectively among male patients, while for IGT and IFG tested by the capillary method, the prevalence was 7.0% and 9.4% respectively. The prevalence of IGT tested by the capillary method was higher than that for IFG, while the prevalence of IGT tested by the laboratory method was higher than that for IFG.

4.5.3 Prevalence of undiagnosed type 2 diabetes

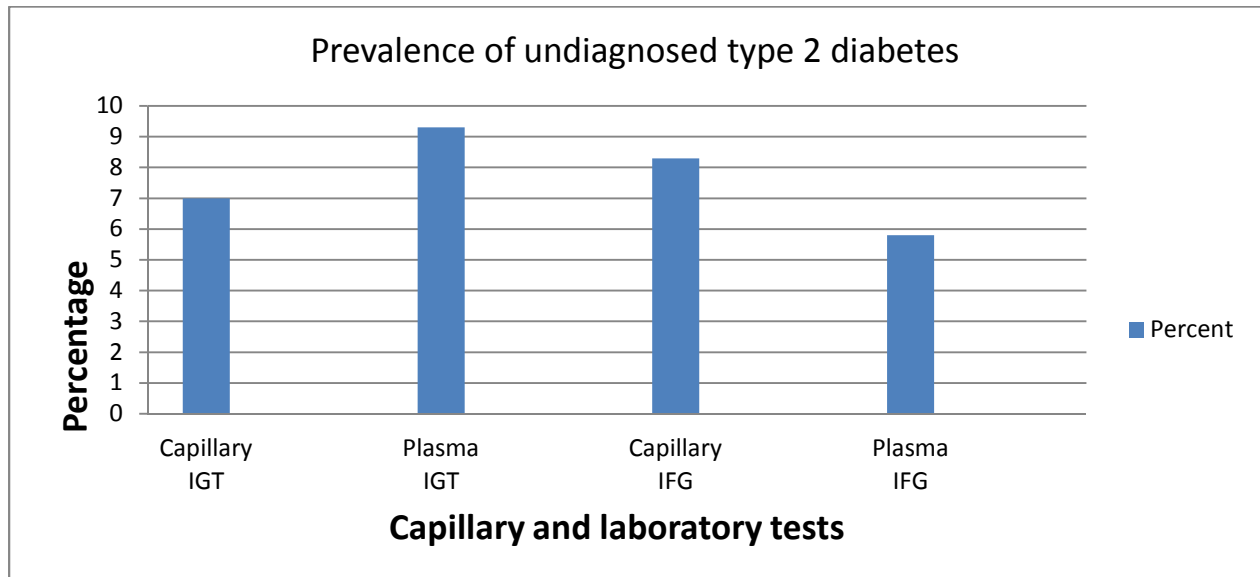


Figure XV: Prevalence of undiagnosed type 2 diabetes (WHO and ADA criteria)

The overall prevalence of undiagnosed type 2 diabetes tested by the laboratory method was 9.3% tested by 2-hour plasma glucose and 5.8% tested by fasting plasma glucose, and the prevalence of undiagnosed type 2 diabetes tested by the capillary method was 7% by 2-hour plasma glucose and 8.3% by fasting plasma glucose.

4.5.4 Prevalence of undiagnosed type 2 diabetes: Female patients

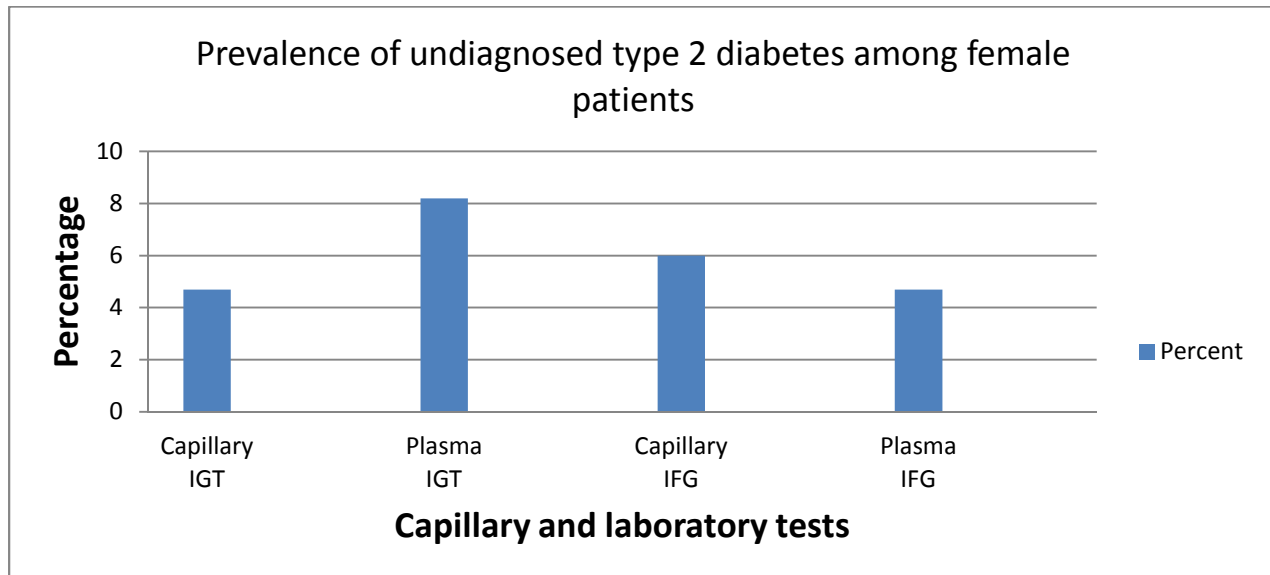


Figure XVI: Prevalence of undiagnosed type 2 diabetes among female patients (WHO and ADA criteria)

The prevalence of undiagnosed type 2 diabetes among females tested by the laboratory method by 2-hour plasma glucose and by fasting plasma glucose was 8.2% and 4.7% respectively, while the prevalence of undiagnosed type 2 diabetes tested by the capillary method was 4.7% tested by 2-hour plasma glucose, and that tested by fasting plasma glucose was 6%.

4.5.5 Prevalence of undiagnosed type 2 diabetes: Male patients

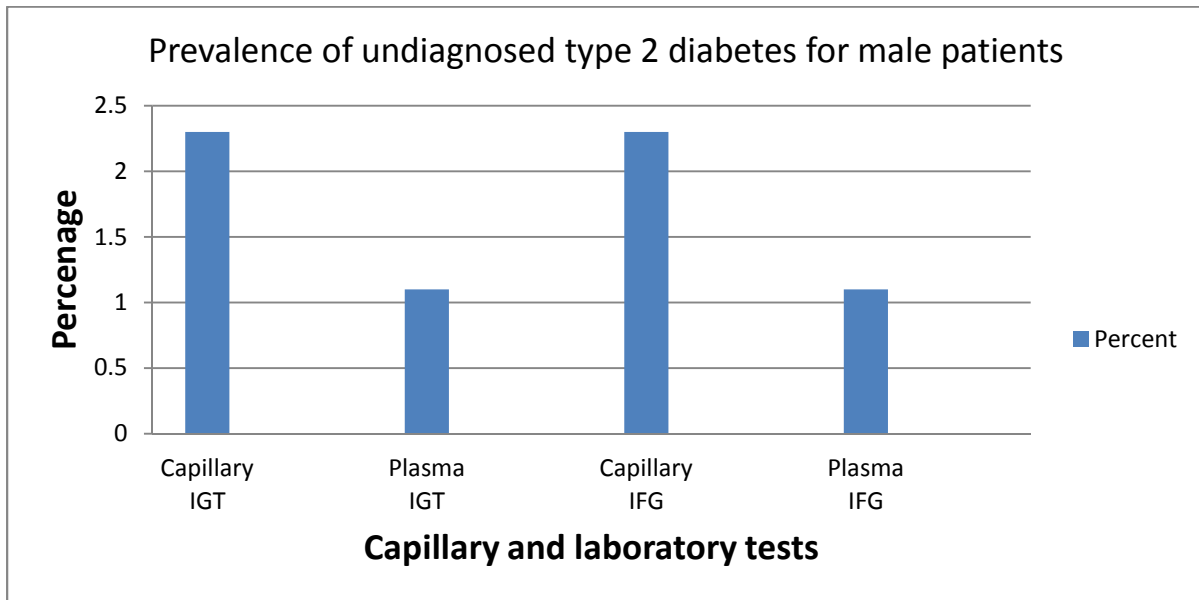


Figure XVII: Prevalence of undiagnosed type 2 diabetes among male patients (WHO and the ADA criteria)

The prevalence of undiagnosed type 2 diabetes among the males was tested by the laboratory method and stood at 1.1% tested by the 2-hour plasma glucose, and at 1.1% tested by fasting plasma glucose. Tested by the capillary method, the prevalence was 2.3% for IGT and 2.3% IFG.

4.5.6 Comparison of screening test

Table VI: p-values of the prevalence of impaired glucose tolerance, impaired fasting glucose and undiagnosed type 2 diabetes by capillary and laboratory methods, using the WHO and ADA diagnostic criteria

| Tests | Females | | Males | | p-value | |
|---|-----------|----|-------|---|---------|-------|
| | No | % | No | % | | |
| Prevalence of impaired glucose tolerance, WHO diagnostic criteria by gender | | | | | | |
| Impaired Glucose Tolerance (IGT), 2-h post 75g Glucose load (OGTT) | Capillary | 20 | 23.5% | 6 | 7.0% | 0.764 |
| | Plasma | 21 | 24.7% | 8 | 9.4% | |
| Prevalence of impaired fasting glucose, ADA diagnostic criteria by gender | | | | | | |
| Impaired Fasting Glucose (IFG), Overnight fasting, 12 hours starved | Capillary | 14 | 16.4% | 8 | 9.4% | 0.514 |
| | Plasma | 15 | 17.6% | 5 | 6% | |
| Prevalence of undiagnosed type 2 diabetes by WHO & ADA diagnostic criteria by gender | | | | | | |
| Impaired Glucose Tolerance (IGT), 2-h post 75g Glucose load (OGTT) | Capillary | 4 | 4.7% | 2 | 2.3% | 0.538 |
| | Plasma | 7 | 8.2% | 1 | 1.1% | |
| Impaired Fasting Glucose (IFG), Overnight fasting, 12 hours starved | Capillary | 5 | 6% | 2 | 2.3% | 1.000 |
| | Plasma | 4 | 4.7% | 1 | 1.1% | |

Fisher Exact Test

The overall prevalence of IGT tested by the laboratory method was 34.1%, which was translated to 24.7% among female patients and 9.4% among male patients, while tested by the capillary method; the overall prevalence was 30.5%, which was translated to 23.5% among female patients and to 7.0% among male patients. The p-value was $p = 0.746$ and those results were not statistically significant.

The overall prevalence of IFG tested by the laboratory method was 23.6%, which was translated to 17.6% for female patients and to 6% for male patients, and tested by the capillary method, the overall prevalence was 25.8%, which was translated to 16.4% for female patients and to 9.4% for male patients. The p-value was $p = 0.514$ and those results were not statistically significant.

The overall prevalence of undiagnosed diabetes tested by the 2-hour plasma glucose was 9.3% and was translated to 8.2% for female patient and to 1.1% for male patients. For the capillary method, the overall prevalence was 7% and translated to 4.7% for female patients and 2.3% for male patients. The p-value was $p = 0.538$. Those results were not statistically significant.

The overall prevalence of undiagnosed diabetes tested by fasting plasma glucose was 5.8%, which was translated to 4.7% for female patients and to 1.1% for male patients, and for fasting plasma glucose tested by the capillary method, the overall prevalence was 8.3%, which was translated to 6% for female patients and to 2.3% for male patients. The p-value was $p = 1.000$ and those results were not statistically significant.

4.7 Sensitivity, specificity, and predictive values

4.7.1 Laboratory method

The screening test by the laboratory method for IGT showed that the sensitivity, specificity, positive and negative predictive values were 34%, 86%, 25%, and 86% respectively. For IFG the result were 24%, 86%, 19%, and 86% respectively. Those results showed that IGT produced more individuals correctly identified with intermediate hyperglycaemia which was 34% - compared to 24% produced by IFG. If IGT was not performed, 10% of the patients would have been missed.

Table VII: The sensitivity, specificity, positive and negative predictive values of a screening test by capillary method between the WHO and the ADA diagnostic criteria

| Screening Test | IGT | | Total | IGT Sensitivity | IGT Specificity | IGT PPV | IGT NPV | IFG | | Total | IFG Sensitivity | IFG Specificity | IFG PPV | IFG NPV |
|----------------|----------|---------|-------|-----------------|-----------------|---------|---------|----------|---------|-------|-----------------|-----------------|---------|---------|
| | Presence | Absence | | | | | | Presence | Absence | | | | | |
| Positive | 29 | 85 | 114 | 34% | 86% | 25% | 86% | 20 | 85 | 105 | 24% | 86% | 19% | 86% |
| Negative | 56 | 530 | 586 | | | | | 65 | 530 | 595 | | | | |
| Total | 85 | 615 | 700 | | | | | 85 | 615 | 700 | | | | |

4.7.2 Capillary method

The screening test by the capillary method for IFG showed that the sensitivity, specificity, positive, and negative predictive values were 26%, 86%, 20.5%, and 86% respectively, while for IGT by the capillary method, the results were 31%, 86%, 23%, and 86% respectively. Those results showed that IGT produced more patients were correctly identified with a sensitivity of 31% compared to that of IFG with a sensitivity of 26%. If IGT by the capillary method had not been performed, 5% of the patients would have been missed.

Table VIII: Sensitivity, specificity, positive and negative predictive values of a screening test by the laboratory method between the WHO and the ADA diagnostic criteria

| Screening Test | IGT | | Total | IGT Sensitivity | IGT Specificity | IGT PPV | IGT NPV | IFG | | Total | IFG Sensitivity | IFG specificity | IFG PPV | IFG NPV |
|----------------|----------|---------|-------|-----------------|-----------------|---------|---------|----------|---------|-------|-----------------|-----------------|---------|---------|
| | Presence | Absence | | | | | | Presence | Absence | | | | | |
| Positive | 26 | 85 | 111 | 31% | 86% | 23% | 86% | 22 | 85 | 107 | 26% | 86% | 20.5% | 86% |
| Negative | 59 | 530 | 589 | | | | | 63 | 530 | 593 | | | | |
| Total | 85 | 615 | 700 | | | | | 85 | 615 | 700 | | | | |

Chapter 5: Discussion

The prevalence of impaired glucose tolerance, impaired fasting glucose and undiagnosed type 2 diabetes at the outpatient department (OPD) of Professor ZK Matthews Hospital was 34.1% and 23.6% respectively, and that for undiagnosed type 2 diabetes discovered during the survey by both the 2 hours 75-g oral glucose load and by fasting plasma glucose, was 9.3% and 5.8% respectively. This is the first study conducted at outpatients department of Professor ZK Matthews hospital in order to establish the impact of the problem. The founding of this study is compared to studies done previously elsewhere.

Evaristo-Neto et al (2010), of their 421 subject in a rural community of Bengo province in Angola, it was found that the prevalence of IGT and undiagnosed diabetes was much lower; 8.1% and 2.8% respectively. This was dramatically very high in the study by Mutebi et al (2012) in Kampala, Uganda; where the prevalence of IGT was 50% and that for undiagnosed diabetes was 24%. In comparison to the founding by Dustan et al (2002) in Australia the prevalence was much lower as like that for the Teheran Lipid and Glucose Study by Hadaegh et al (2008), where the prevalence of undiagnosed diabetes, IGT and IFG was 4.9%, 6.7%, and 7.3% which is lower in comparison to this study. Others studies in South Africa, shows higher rates depending on ethnicity.

Groenewald et al (2009) in Springfontein and Trompsburg the Free State province of South Africa, found that the prevalence of undiagnosed diabetes and IFG was 37.5% and 6.3%, however, this was lower to that found by Motala et al (2008) in the Ubombo district of rural northern KwaZulu-Natal where the prevalence of IGT was lower 6.4% while undiagnosed diabetes was 84% which is very higher compared to the founding of this study.

In Bellville, Cape Town, South Africa; Erasmus et al found among coloured population that the prevalence of IGT, IFG, and undiagnosed diabetes was 15.3%, 4.4% and 18.1% respectively, which is much lower compared to the founding in this study and also contradicted the fact that previous study reported that Coloured population in South Africa has a highest prevalence of hyperglycaemia. Mutebi et al reported that the higher rates of undiagnosed diabetes in developing nations are due to the absence of rigorous screening, leaving many patients undiagnosed.

In this study, the contributing risk factors such as BMI over 25 kg/m², the diastolic blood pressure over 90 mmHg and the systolic blood pressure over 140 mmHg was a significant risk factors, while the waist

circumference (WC) and the waist-to-hip ratio (WHR) among female and male patients provided a predictive risk factors of developing IGT, IFG, or undiagnosed type 2 diabetes.

Elbagir and colleagues showed strong association between family history of diabetes and IGT, IFG and undiagnosed diabetes. Omar et al shows that a trend increasing of impaired glucose tolerance as blood pressure rose. Faeh et al (2007) reported that overweight, obesity and genetic predisposition are the sole foundation of developing abnormal glucose tolerance. The WHO also reported that a number of overweight people is in the rise worldwide in 2013 and will form an epidemic of obesity by 2015.

The rise in the prevalence of undiagnosed type 2 diabetes and impaired glucose tolerance, which accounts for the majority of cases of acute or chronic hyperglycaemia globally, has been linked to the increase in the prevalence of obesity (Ogunbanjo, 2013). Similarly, Heikes et al (2008) reported that undiagnosed type 2 diabetes and impaired glucose tolerance was high due to a strong association with anthropometric risks, age, race or ethnicity, positive family history of diabetes, and hypertension.

Mustafa et al (2011) reported that the missing of a large proportion of undiagnosed cases of pre-diabetes and diabetes reflects the lack of public awareness of the disease. Amod et al (2012) reported that the 2003 Demographic and Health Survey showed that 30% of South Africans are overweight or obese. Van Zyl et al (2010) on an observational study, reported that 56% of South African women compared to 29% of men were overweight or obese, that the physical activity level of adults in SA is less than one-third, meaning that about 46% of all SA was reported to be physically inactive, resulting in weight gain and an increase in BMI, that physical activity such as exercise may increases insulin sensitivity.

The study found that female patients were majority participants and represented 72% of subjects compare to male patients who represented only 28%. Female patients had an increased risk or had a higher risk of developing IGT, IFG or undiagnosed diabetes than male patients. The study demonstrated that there was a strong relationship between obesity (grade I, II, and III), WC, WHR and IGT, IFT, and undiagnosed diabetes, which were related to BMI, alcohol, poor diet, hypertension, physical inactivity, smoking and alcohol consumption as risk factors.

Abu-Rmeileh et al (2013) reported that the prevalence of smoking habit as a contributor factor of IGT, IFG or diabetes was very high among Palestinians men, namely 53.7%, but very low among Palestinian women - only 5.2%. Similarly, a study by Makinga et al (2013) in Lesotho reported that some lifestyle habits are considered to be risks factors for IGT or diabetes. These include smoking, drinking alcohol, a low level of

physical exercise and a high fat diet. In a similar study by Mutebi et al, it was demonstrated that there was a significant association between alcohol consumption and IGT. The relationship between alcohol consumption and IGT is multi-factorial and may involve pancreatitis with the destruction of α - and β - cells responsible of insulin secretion.

Levitt et al (1999) also demonstrated that low total energy expenditure was a significant risk factor for diabetes and impaired glucose tolerance. Van der Merwe (2004) indicated that the greatest population attributable risk of impaired glucose tolerance or undiagnosed type 2 diabetes, occurs in SA people with a waist circumference > 102 cm in men and > 88 cm in women, age > 40 years, African and Asian ethnicity, and having a sedentary life-style, urbanisation, and unhealthy eating.

This study demonstrated that the prevalence of IGT, IFG and undiagnosed diabetes was high, many patients did not know having an abnormal glucose tolerance and furthermore some patients were discovered having undiagnosed type 2 diabetes during the survey. Amod et al (2012) informed that the insidious and initially asymptomatic nature of the disease results in patients not seeking early medical attention until complications become apparent.

During the screening test in this study, it was demonstrated that using the WHO diagnostic criteria would identified more patients with abnormal glucose tolerance than the ADA criteria do. Therefore the sensitivity, specificity, positive and negative predictive values were compared. The test done by the laboratory method were 34%, 86%, 25%, and 86% respectively for IGT and 24%, 86%, 19%, and 86% for IFG. There was a difference of 10% in sensitivity between the two tests. Similarly, Shobha et al (2004) reported that the fasting plasma glucose level is more reproducible than 75-g oral glucose tolerance test and Heikes (2008) also informed that the 75-g oral glucose was still the best test to confirm the diagnostic. Shaw (1999) indicated that screening by the criterion of fasting plasma glucose alone would identify fewer people who would subsequently progress to type 2 diabetes than the oral glucose tolerance test would.

Chapter 6: Conclusion and recommendations

6.1 Conclusion

The study found very higher rates of impaired glucose tolerance, impaired fasting glucose, and undiagnosed diabetes. The anthropometric profile of patients was characterised by a high Body Mass Index (BMI), a high waist circumference (WC), and a high Waist-to-Hip Ratio (WHR). The rise in abnormal glucose tolerance and undiagnosed diabetes is associated with the rise in the prevalence of obesity among patients attending outpatient department at Professor ZK Matthews Hospital. Family history of hypertension, family history of diabetes, poor diet, sedentary lifestyle, alcohol consumption, smoking habit, physical inactivity and hypertension among patients were significantly associated with the high prevalence of IGT, IFG, and undiagnosed type 2 diabetes. The anthropometric profile and risk factors of patients dictates the prevalence of impaired glucose tolerance, impaired fasting glucose and undiagnosed type 2 diabetes mellitus. There is a strong case for screening patients at risk of developing IGT, IFG or undiagnosed type 2 diabetes. Generally most patients living with impaired glucose tolerance impaired fasting glucose and undiagnosed type 2 diabetes; remains unidentified, undetected, unscreened, undiagnosed, and untreated. It is known that the transition period of impaired glucose tolerance is long (over 10 years), it is silent and asymptomatic. Generally during this period, both the patient and the clinicians are not aware until rigorous screening test is done. Exception to the genetic susceptibility; it is possible to modify risk factors and lifestyle changes of individuals to control the rise in prevalence of IGT, IFG or undiagnosed type 2 diabetes among patients having the risk. It is also possibly to reduce the risk of long-term complications; even to bring the clock back to normal if action is taken timously.

6.2 Recommendations

- The founding of this research may be limited to the study setting
- A further research will need to be done using a larger data including dislipidaemia profile
- Health professionals should follow the guidelines on diabetes screening which is provided by the society of metabolism, endocrinology and diabetes of South Africa
- A holistic approach is mandatory for prevention, intervention and health promotion in order to reduce morbidity, mortality and disability
- Early rigorous screening has a merit in order to prevent future complications (limbs amputation, stroke, kidney failure, loss of vision, peripheral vessels diseases)
- To fight overweight and obesity by introducing physical activity and healthier diet
- Abnormal glucose tolerance and diabetes is a concern for all: physicians, nurses clinicians, nurses educators, social workers, physiotherapists, dieticians, health promoters and home based carers

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Appendix

English Informed Consent

Title:

The prevalence of impaired glucose tolerance, impaired fasting glucose, and undiagnosed type 2 diabetes among middle-aged adults attending outpatient department at Prof ZK Matthews Hospital, Barkley West, Northern Cape Province, South Africa.

I have read the information on */heard the aims and objectives of* the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I understand that participation in this Clinical Trial / Study / Project* is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor.

I know that this Trial / Study / Project* has been approved by the Medunsa Campus Research and Ethics (MCREC), University of Limpopo (Medunsa Campus) / Dr George Mukhari Hospital. I am fully aware that the results of this results of this Trial / Study / Project* will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this Trial / Study / Project*.

| | | |
|------------------------|-------------|-----------------------------|
| | | |
| Name of patient | | Signature of patient |
| | | |
| Place. | Date | Witness |

Statement by the Researcher

I provided written information regarding this Project

I agree to answer any future questions concerning the Project as best as I am able.

I will adhere to the approved protocol.

| | | | |
|-------------------------|------------------|-------------|--------------|
| | | | |
| Dr. T.G. Kitenge | Signature | Date | Place |

Afrikaans informed consent

Titel: Die voorkoms van versteurde glukose toleransie, versteurde vastende glukose en ongediagnoseerde tipe 2 diabetes onder middeljarige volwassenes wat die buite patient afdeling van Professor Z.K. Matthews Hospitaal, Barkley Wes, Noord –Kaap provinsie, Suid Afrika besoek.

Ek het die inligting in verband met die beoogde studie gelees*/het die doelwitte en oogmerke van die beoogde studie aangehoor* en is die geleentheid gegun om vrae te stel asook voldoende tyd toegelaat om oor die aangeleentheid te besin. Die doelwit en oogmerke van die studie is duidelik genoeg vir my. Ek is geensins onder enige druk geplaas om deel te neem nie.

Ek verstaan dat deelname aan hierdie Kliniese Eksperiment/Studie/Projek* geheel en al vrywillig is en dat ek te eniger tyd daarvan kan onttrek sonder om enige redes aan te voer. Dit sal geen invloed hê op die gereelde behandeling van my toestand nie, en sal ook nie die behandeling wat ek van my eie dokter ontvang, beïnvloed nie.

Ek is bewus daarvan dat hierdie Eksperiment/Studie/Projek* goedgekeur is deur die 'Medunsa Campus Research and Ethics Committee (MCREC)', Universiteit van Limpopo (Medunsa-kampus)/Dr George Mukhari Hospitaal. Ek is ten volle bewus daarvan dat die uitslae van hierdie Eksperiment/Studie/Projek* aangewend sal word vir wetenskaplike doeleindes, en gepubliseer mag word. Ek stem daartoe in, met dien verstande dat my privaatheid gewaarborg is.

Hiermee verleen ek toestemming om deel te neem aan hierdie Eksperiment/Studie/Projek*.

.....

Naam van pasiënt/vrywilliger Handtekening van pasiënt of voog

Plek / Datum / Getuie

Verklaring deur Navorser

Ek het mondelingse en/of skriftelike* inligting ten opsigte van hierdie Eksperiment/Studie/Projek* voorsien. Ek verklaar myself bereid om enige toekomstige vrae ten opsigte van die Eksperiment/Studie/Projek* na die beste van my vermoë te beantwoord. Ek sal myself onderwerp aan die goedgekeurde protokol.

.....

Naam van Navorser

Handtekening

Datum

Plek

*Skrap waar nie van toepassing nie.

INFORMATION LEAFLET FOR PARTICIPANTS

Title: The prevalence of impaired glucose tolerance, impaired fasting glucose and undiagnosed type 2 diabetes among middle aged adults attending outpatients department at Professor Z.K. Matthews Hospital, Barkley West, Northern Cape Province, South Africa.

Introduction

You are invited to volunteer for a study/research. This information leaflet will assist you in deciding if you would like to participate, before you agree to take part in this study you should fully understand what is involved. If you have any questions which are not fully explained in this leaflet, do not hesitate to ask the researcher.

Dr. Kitenge T.G., Cell: 0845455360

Purpose and objectives of the study

The aim of the study is to determine the prevalence of the prevalence of impaired glucose tolerance, impaired fasting glucose and undiagnosed type 2 diabetes among middle aged adults, attending outpatient department at Professor Z.K. Matthews Hospital, Barkley West, Northern Cape Province, South Africa.

The following are objectives of the study:

- To describe the demographic characteristics of patients with abnormal glucose tolerance.
- To determine risks factors influencing abnormal glucose tolerance.
- To determine positive predictive value, sensitivity and specificity of the test.
- To determine the diagnostic test the most identified and produced more individuals with abnormal glucose.

The Rights as a Patient:

The following rights will be observed

- Rights not to be harmed
- Voluntary participation
- Right to confidentiality
- Right to anonymity
- Right to informed consent

Risks involved

There are no foreseeable risks. All information obtained will be strictly confidential. The data collected for the study will not be linked to your name. The study may be published in the scientific journal.

BYLAE B: INFORMASIE PAMFLET VIR DEELNEMERS

Titel: Die voorkoms van versteurde glukose toleransie, versteurde vastende glukose en ongediagnoseerde tipe 2 diabetes onder middeljarige volwassenes wat die buite patient afdeling van Professor Z.K. Matthews Hospitaal, Barkley Wes, Noord –Kaap provinsie, Suid Afrika besoek.

Inleiding

U word hartlik uitgenooi om vrywilliglik deel te neem aan 'n studie. Hierdie inligtings blaadjie sal u in staat stel om te besluit of u wil deelneem, voordat u besluit om deel te neem aan die studie moet u eerste ten volle verstaan wat dit behels. As u enige vrae het wat nie hierin tenvolte verduidelik word nie moet u nie huiwer om die navorser te kontak nie.

Dr. Kitenge T.G., Cell: 0845455360

Doel van die studie

Die doel van die studie is om te bepaal wat die voorkoms van versteuring in glukose toleransie en vastende bloedglukose sowel as ongediagnoseerde diabetes tipe 2 onder middeljarige volwassenes wat die buite patient afdeling van Professor Z.K. Matthews Hospitaal, Barkley Wes, Noord –Kaap provinsie, Suid Afrika besoek. Die volgende is die doelwitte van die studie:

- Om die demografiese karaktertrekke van patiente wat die gevaar loop om versteurde glukose te ontwikkel te beskryf.
- Om die risiko faktore wat verswakte glukose toleransie beïnvloed te bepaal.
- Om die voorkoms van tipe 2 diabetes te bepaal
- Om te bepaal die verwantskap tussen risiko faktore en verswakte glukose verdraagsaamheid.
- Om die ontwikkeling van tipe 2 diabetes as gevolg van 'n verswakte glukose toleransie te voorspel.

Die regte van die patient:

Die volgende regte van die patient sal waargeneem word

- Die reg om nie benadeel te word nie
- Vrywillige deelname
- Reg tot vertroulikheid
- Reg om anoniem te bly
- Reg tot ingeligte toestemming

Risikos betrokke

Daar is geen voorsienbare risikos. Alle inligting verkry is ten volle vertroulik. Die data wat ingesamel word sal nie aan u naam gekoppel word nie. Die studie mag in die wetenskaplike dagblad verskyn.

UNIVERSITY OF LIMPOPO
Medunsa Campus



MEDUNSA RESEARCH & ETHICS COMMITTEE

CLEARANCE CERTIFICATE

MEETING: 08/2012
05/2013

PROJECT NUMBER: MRECHS/240/2012: PG

PROJECT:

Title: The prevalence of impaired glucose tolerance, impaired fasting glucose, and undiagnosed type diabetes among middle aged adults attending outpatients department at Professor ZK Mathews Hospital, Barkley West Frances Baard District Northern Cape Province, South Africa.

Researcher: Dr TG Kitenge
Supervisor: Dr Mpolokeng
Hospital Superintendent: Dr Kazaji
Department: Medical Sciences, Public Health & Health Promotion
School: Health Sciences
Degree: MPH

DECISION OF THE COMMITTEE:

MREC approved corrections in names & title

DATE: 11 October 2012
06 June 2013

PROF GA OGUNBANJO
CHAIRPERSON MREC

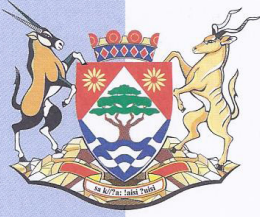


The Medunsa Research Ethics Committee (MREC) for Health Research is registered with the US Department of Health and Human Services as an International Organisation (IORG0004319), as an Institutional Review Board (IRB00005122), and functions under a Federal Wide Assurance (FWA00009419)
Expiry date: 11 October 2016

Note:

- i) Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee.
- ii) The budget for the research will be considered separately from the protocol. PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.





DEPARTMENT OF HEALTH
LEFAPHA LA BOITEKANELO
ISEBE LEZEMPILO
DEPARTEMENT VAN GESONDHEID

Department of Health
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KIMBERLEY
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Isalathiso :
Verwysings :

Date :
Lettha : 13 December 2012
Umhla :
Datum :

NC PHREC Reference Number: NC2012/007

**TITLE: THE PREVALENCE OF IMPAIRED GLUCOSE TOLERANCE;
IMPAIRED FASTING GLUCOSE, AND UNDIAGNOSED TYPE 2 DIABETES
AMONG MIDDLE AGE ADULTS ATTENDING OUTPATIENT DEPARTMENT
AT PROFESSOR ZK MATTHEWS HOSPITAL; BARKLY WEST, NC SA**

Dear TG Kitenge

The application to conduct the study was received and has been considered by the Northern Cape Provincial Health Research and Ethics Committee.

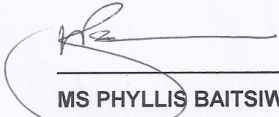
Approval is hereby granted to conduct the above-mentioned research in the Northern Cape.

The following conditions have to be noted:

1. The research project shall be conducted at no cost to the Northern Cape Department of Health
2. Northern Cape Senior Management Committee will be briefed on the outcome of the study prior to publishing.

The Committee wishes you the best as you conduct your study

Yours Sincerely


MS PHYLLIS BAITSIWE
CHAIRPERSON: PHREC

12/12/2012
DATE



