DIAGNOSTIC ACCURACY OF WAIST CIRCUMFERENCE IN DETECTING METABOLIC SYNDROME IN TYPE 2 DIABETES MELLITUS PATIENTS

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DECLARATION

I declare that this dissertation is my own work. It is being submitted for the Master's degree in Internal Medicine at the University of Zambia, Lusaka. It has not been submitted before for any degree or examination at this or any other university.

Signed:…….

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Supervisor

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Head of department

ABSTRACT

TITLE: Diagnostic accuracy of waist circumference in detecting Metabolic Syndrome in type 2 Diabetes Mellitus patients

Background: Metabolic Syndrome (MetS) is a constellation of clinical features that increase cardiovascular morbidity and mortality in individuals. Up-to-date, there is no cheap, single surrogate test for MetS and current diagnostic criteria for the syndrome use scoring systems which are laborious, expensive and thus not adaptable to low resource countries such as Zambia. In this study, waist circumference measurement alone was proposed as a simpler surrogate test and thus its diagnostic accuracy for MetS in type 2 Diabetes Mellitus patients was assessed.

Objectives*:* To determine the diagnostic accuracy of waist circumference measurement alone in detecting Metabolic Syndrome (MetS) in type 2 Diabetes Mellitus (Type 2 DM) patients.

Materials and Methods: This was a cross-sectional hospital based study of 400 medical outpatients with type 2 DM. The National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) was used as the standard diagnostic test and components of metabolic syndrome that were measured included waist circumference, blood pressure, fasting blood sugar, fasting serum triglycerides and HDL cholesterol. Abdominal obesity was defined as waist circumference ≥ 94cm for men and ≥80cm for women. The sensitivity and specificity of waist circumference as compared with the NCEP ATP III definition were determined.

Results: The prevalence of MetS was 73% (91% in women and 50% in men; $p<0.001$).The presence of abdominal obesity had sensitivity of 90% in women and 92% in men and specificity of 86% in women and 91% in men, in detecting metabolic syndrome. The area under the receiver operating characteristic curve was 0.883.

Conclusions: There was a high prevalence of MetS among type 2 DM patients in the study. When used alone, waist circumference measurement has a relatively good diagnostic accuracy for MetS in type 2 DM patients. Therefore it can be used alone as a simpler and cheaper surrogate test for diagnosing MetS in type 2 DM patients in resource limited countries.

DEDICATION

To my parents,

Mr. Edmond Chanda

And

Mrs. Elena Chanda

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LIST OF ABBREVIATIONS

MetS	Metabolic Syndrome
Type 2 DM	Type 2 Diabetes Mellitus
HDL	High Density Lipoprotein Cholesterol
WHO	World Health Organization
NCEP ATP III	National Cholesterol Education Program Adult Treatment Panel III
WHR	Waist Hip Ratio
USA	United State Of America
NIH	National Institute of Health (USA)
IDF	International Diabetes Federation
UTH	University Teaching Hospital
MOH	Ministry Of Health (Zambia)
WC	Waist circumference
SD	Standard Deviation
Cl	Confidence Level
AUC	Area under the Curve
BMI	Body Mass Index

CHAPTER 1

1.0 INTRODUCTION

Metabolic Syndrome (MetS) is the clustering of three or more risk factors for cardiovascular disease in one individual. These risk factors include type 2 Diabetes Mellitus (Type 2 DM), high blood pressure, high serum triglycerides, low levels of High Density Lipoprotein cholesterol (HDL) and abdominal obesity [1]. Each individual component of the MetS carries a grave risk for severe vascular events and a combination of three or more in one person has a synergistic effect [2]. Therefore, recognizing MetS in patients is important because it acts as a clinical tool for identifying individuals at high risk of cardiovascular morbidity and mortality so as to initiate lifestyle and medical interventions early enough to avert complications[3].

Even though a lot of research has been done on insulin resistance and the MetS among type 2 DM patients in developed countries, there is paucity of published material in Africa [4]. Few countries have carried out national population surveys of the MetS and thus world prevalence is not known [5].

Prevalence and presentation of MetS has been observed to vary from one region to another and even with the diagnostic criteria used [1,6,7,8]. Therefore, studies done in other countries may not apply to Zambia.

Since its first official definition by the World Health Organization (WHO) in 1999[1,4,8]the diagnostic criteria for MetS has undergone a lot of modifications [2] incorporating clinical evidence by professional organizations with the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) being the most recent and widely used criteria.[1] Despite these efforts, laborious and expensive scoring systems [1]are still used to diagnose MetS because no single, cheap and easy to use surrogate test has been developed to diagnose the syndrome.

In this study, waist circumference measurement alone was proposed as a simpler and cheaper surrogate test for detecting MetS in type 2 DM patients and thus its diagnostic accuracy was determined.

CHAPTER 2

2.0 LITERATURE REVIEW

2.1 Type 2 Diabetes Mellitus and Metabolic Syndrome

The prevalence of MetS increases with increasing worldwide prevalence of type 2 DM [9]. Furthermore, type 2 DM is included in all diagnostic criteria for MetS[1]and it is estimated that about 75 percent of patients with type 2 DM may have the MetS[1]and if type 2 DM is not already present, MetS is a strong predictor for its development[10].

2.2 Abdominal Obesity and Metabolic Syndrome

Although there are different definitions of the MetS, abdominal obesity is a prominent clinical feature of the MetS and it plays a central role in its development [9]. Additionally, abdominal obesity measured by waist circumference is a risk factor for insulin resistance, type 2 DM and other components of the MetS [1] and it also has a higher correlation with metabolic abnormalities of MetS and cardiovascular disease risk than a high body mass index [4].

The world health organization (WHO) favours the use of waist circumference alone rather than waist: hip ratio (WHR) to assess abdominal obesity because it is a simpler measure and is closely related to cardiovascular disease risk [11].

Some authorities such as the International Diabetes Federation have even further stated that a patient can only have MetS if he/she has abdominal obesity among other features[1] with a study in Cameroon suggesting that abdominal obesity is responsible for the prevalence of MetS in Sub-Saharan Africa [9,12].

2.4 Prevalence of Metabolic Syndrome

In countries where studies have been done the prevalence of MetS ranges from less than 10 percent to more than 80 percent, depending on age, region, urban or rural environment, ethnicity, and definition of the metabolic syndrome used[13]. For example, in the USA, the age adjusted prevalence was 34 percent for men and 35 percent for women with the highest prevalence observed in Native Americans (60 percent in women and 45 percent in men) [1].

In France a cohort, reported prevalence of less than 10 percent in those 30-64 years but 17.5 percent in those in the 60-64 year age range [1].

A study in Iraq found 86 percent prevalence among patients with type 2 DM and the prevalence was higher in women[14], whilst a study in neighbouring Saudi Arabia found a lower prevalence of 56 percent with a higher prevalence in males[15].

Closer to home in Africa, a Nigerian study found 51 percent prevalence among type 2 DM patients and was high in women[2]. On the other hand, a study in South Africa found prevalences of 46.5 percent and 74.1 percent among blacks and whites respectively and the prevalence was higher in women [16].

2.5 Lifestyle interventions

The goal of treatment for MetS is to prevent or slow down the progression of diabetes, hypertension, and cardiovascular disease [1]. Since obesity is the driving force behind MetS, lifestyle interventions and/or pharmacotherapy are the mainstay of treatment for the MetS [1] with a weight loss of 5% to 10% leading to significant reduction in morbidity and mortality [17]. For weight reduction the most important component is caloric restriction with increased physical activity being important for maintenance of weight loss [1].

CHAPTER 3

3.0 STUDY JUSTIFICATION

The prevalence of MetS in Zambia is not known and the diagnostic accuracy of waist circumference measurement alone for detecting MetS among type 2 DM is not known.

The MetS increases cardiovascular morbidity and mortality in patients with type 2 DM and its prevalence varies from one population to another and even within the same population and with the diagnostic criteria used[1,2,3,4]. Therefore, study findings in other countries may not apply to Zambia. Furthermore, the morbidity and mortality associated with MetS is preventable and can be reduced by early recognition and intervention [1].

There is increasing evidence that obesity is central to the development of MetS and that the current diabetes and cardiovascular disease epidemic is driven by the obesity epidemic [1, 9, 17]. The brown visceral abdominal fat is currently believed to be responsible for the cardiovascular complications associated with obesity [1]. Waist circumference measurement is a simple and standard method of documenting abdominal obesity and it is one of the prominent components of MetS [1]. In fact, authorities such as the International Diabetes Federation (IDF) have stated that a patient can only have MetS if he/she has obesity among other clinical features [1] and a study in Cameroon [9,17] has even suggested that abdominal obesity may be behind the current MetS epidemic in Sub Sahara Africa.

In the most recent and widely used diagnostic criteria (NCEP ATP III) [1] waist circumference is still being used in the context of scoring systems which are laborious and expensive, thus not adaptable to resource limited countries such as Zambia. This underscores the need to develop a single surrogate test for the diagnosis of MetS and in view of the above evidences and theories, this study proposed the use of waist circumference measurement alone to fulfill that purpose and thus its diagnostic accuracy was tested against the NCEP ATP III among medical outpatients with type 2 DM at UTH, Lusaka, Zambia.

The findings of this study are important because they will provide baseline data for future and even larger epidemiological studies and furthermore findings will be forwarded to the ministry of health (MOH) for possible formulation of clinical guidelines for the MetS and thus adding to the body of knowledge in medicine.

3.1 MAIN OBJECTIVE

To determine the diagnostic accuracy of waist circumference measurement alone in detecting MetS in type 2 DM patients at UTH.

3.1.1 Specific objectives;

1. To diagnose MetS among medical outpatients with type 2 DM,
2. To determine prevalence of MetS among medical outpatients with type 2 DM
3. To compute sensitivity, specificity and predictive values.

CHAPTER 4

4.0 MATERIALS AND METHODS

4.1 Methods

This cross sectional study (conducted in November and December 2010) recruited 400 medical outpatients (at clinic 5, UTH, Lusaka, Zambia) already confirmed to have type 2 DM by the attending physicians. The prevalence formula ($\mathbf{N=Z^2 P (1-P)/d^2}$) was used to calculate the sample size and since the prevalence of MetS was not known a prevalence of 50% was assumed at 95% CI to arrive at the sample size. Patients were identified using file review as they were waiting to be seen at clinic 5 in the morning. On average, about 10-15 diabetics are seen pay day in clinic 5 and in order to increase the enrolments to about 20-25 pay day, even type DM patients who had just come to make appointments were included in the study. Convenient sampling by recruiting consecutive type 2 DM patients that consented to participate in the study was employed. Demographic data focused on past medical and drug history on diabetes and hypertension was obtained after which a physician examined the patients to determine waist circumference, blood pressure, height, weight and to exclude confounders such as ascites and pregnancy. To exclude inter-observer bias only one physician was used for clinical examinations.

Waist circumference was measured in centimeters using a tape measure at the level of the umbilicus without top garments in the supine position.

Blood pressure was measured using a mercury sphygmomanometer after patients had rested for at least 10 minutes. For each patient two blood pressure readings were taken 5 minutes apart, one in the sitting position and the other in the supine position and the final reading was the average of the two readings.

Height was measured in meters without head dress or footwear and weight was measured in kilograms without footwear. Body mass index was calculated by dividing height squared into the weight.

Diabetic patients came to the clinic already fasted and blood samples were collected in heparinized bottles and labeled with corresponding numbers on hard copy data collection

forms (from 1 to 400 respectively) and sent to the focal person at the UTH biochemistry laboratory for determination of serum triglycerides and HDL-cholesterol levels using an Olympus AU 400 analyzer.

Clinical and laboratory data thus obtained was entered onto corresponding hard copies of data sheets.

4.1.1 Inclusion Criteria

1. Known type 2 DM patients.

4.1.2 Exclusion Criteria

1. Failure to give consent
2. Abdominal mass
3. Pregnant women
4. Ascites

4.1.3 Independent Variables used for diagnosis of MetS

- Waist circumference (cm)
- Blood pressure (mmHg)
- Fasting plasma triglycerides (mmol./L)
- Fasting plasma HDL-cholesterol (mmol./L)

4.1.4 Dependent variable

Presence of Metabolic Syndrome

4.1.5 Other variables that were assessed included;

- Age (years)
- Sex (M/F)
- Height (m)
- Weight (Kg)
- BMI(Kg/m^2)

4.4 Study definitions

For the purpose of this study the following definitions were used.

4.4.1 Case definition of type 2 Diabetes

For the purpose of this study, type 2 DM was defined as any patient diagnosed with type 2 diabetes by attending physicians after the age of 30 years.

4.4.2 Case definition of Metabolic Syndrome

Since all study participants had type 2 DM only two of the following NCEP ATP III criteria were needed to establish the diagnosis of metabolic syndrome,

1. Abdominal obesity with waist circumference for men ≥ 94cm women ≥80 cm,

2. Blood pressure > 130 systolic and/or >85mmHg diastolic on at least two or more occasions or previous diagnosis of hypertension or specific medication.

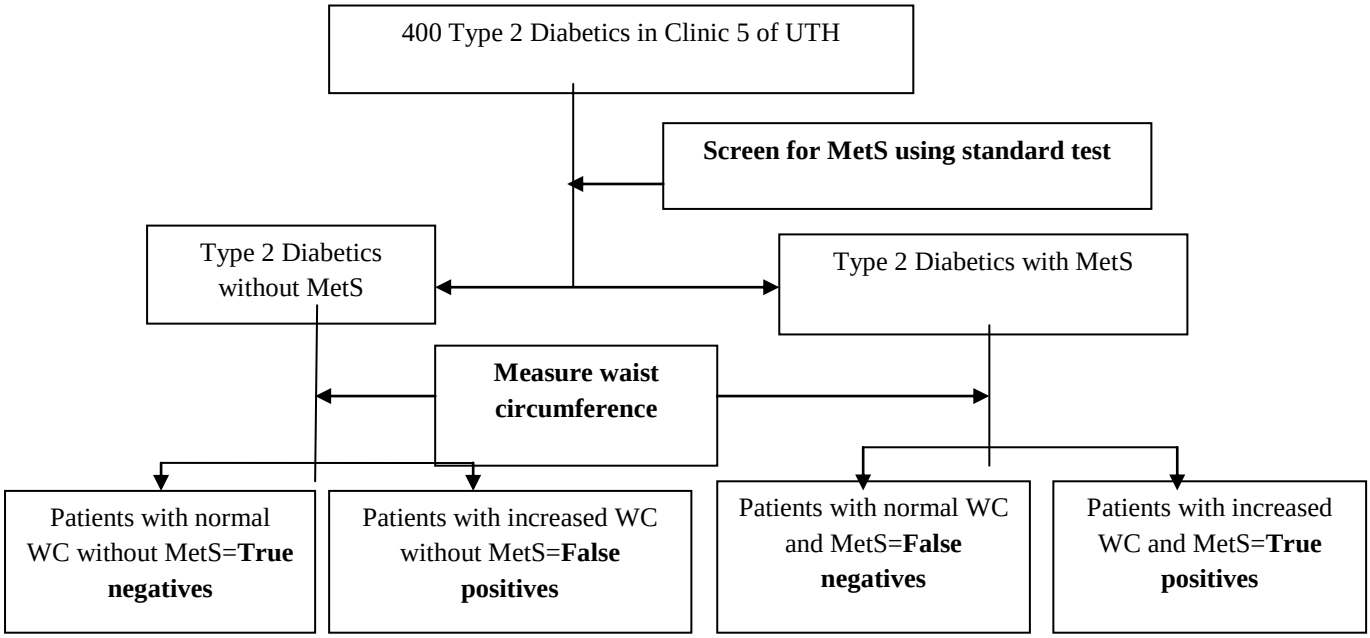
3. Fasting triglycerides ≥1.7mmol./L, or specific treatments.

4. Fasting HDL-cholesterol <0.9mmol/L in males, <1.0mmol/L in females

4.6 Data Entry

The data from the data collection form was then entered electronically onto a predesigned data master sheet on Epi Info version 3.3.2 program.

Fig. 1: Flow chart of patients in study



4.7 Data Analysis

Continuous variables were presented as mean± standard deviation (SD). Unpaired student t-test was used to determine the differences between continuous variables in males and females. The chi-square test was used to asses associations of categorical variables with MetS and the level of statistical significance was taken as $p<0.05$ at 95% Cl.

Prevalence, specificity, sensitivity and predictive values were computed using Epi Info version 3.3.2 and results were presented as tables.

The age distribution of participants with MetS was presented as a bar chart.

Secondary analysis was done plotting sensitivities against 1-sensitivity for different cut offs for waist circumference and then calculating the area under the curve (AUC) using Epi Info version 3.3.2.

CHAPTER 5

5.0 RESULTS

Out of the 400 patients with type 2 diabetes mellitus that were recruited into the study 222 (55.5%) were women and 178 (44.5%) were men. The age range was 38- 96 years with a mean of 59.3±11.1 (SD) years.

More than half (62.3%) of the participants were on oral hypoglycemic drugs and 150 (37.5%) were on insulin. The mean fasting blood sugar and BMI were 8.97±3.8 (SD) and 25.7±5.2 (SD) respectively. Refer to table 1 for baseline characteristics.

Table 1: Descriptive characteristics

	Total (n=400)	**Women (n=222)**	**Men (n=178)**	**P value**
Age (Years)	**59.30 ± 11.13**	**60.60 ± 10.35**	**57.70 ± 11.86**	**0.009**
Height (m)	**1.63 ± 0.23**	**1.61 ± 0.30**	**1.65 ± 0.06**	**0.115**
Weight (Kg)	**67.50 ± 14.84**	**65.80 ± 11.72**	**69.50 ± 17.82**	**0.014**
SBP (mmHg)	**133.10 ± 24.22**	**133.00 ± 24.83**	**133.30 ± 23.51**	**0.915**
DBP (mmol./L)	**82.90 ± 13.70**	**82.70 ± 12.34**	**83.10 ± 15.28**	**0.795**
BMI (Kg/m^2)	**25.70 ± 5.21**	**25.90 ± 4.71**	**25.50 ± 5.78**	**0.450**
Waist circumference (cm)	**90.90 ± 14.84**	**93.10 ± 13.36**	**88.10 ± 16.12**	**<0.001†**
Fasting blood sugar (mmol./l)	**8.97 ± 3.80**	**9.06 ± 3.30**	**8.85 ± 4.36**	**0.586**
Serum Triglycerides (mmol./L)	**1.77 ± 1.61**	**1.81 ± 1.82**	**1.71 ± 1.30**	**0.583**
Serum HDL (mmol./L)	**1.30 ± 0.87**	**1.38 ± 0.99**	**1.21 ± 0.68**	**0.058**

All data are means ± SD

†Significant p value

Table 2 Prevalence of MetS and its components among type 2 DM patients.

	Total (n=400)	**Women (n=222)**	**Men (n=178)**	**P Value**
MetS	**290 (73)**	**201 (91)**	**89 (50)**	**<0.001†**
Abdominal obesity	**273 (68)**	**183 (82)**	**90 (51)**	**<0.001†**
Hypertension	**321 (80)**	**204 (92)**	**117 (66)**	**<0.001†**
Hypertriglyceridaemia	**125 (31)**	**78 (35)**	**47 (31)**	**0.061**
Low HDL	**82 (21)**	**57 (26)**	**25 (14)**	**0.004†**

All data are n (%)
†Significant p value

The most common component of MetS in this population was hypertension (80%) followed by abdominal obesity (68%) with low HDL having the lowest prevalence (25%). The difference in prevalence between men and women was statistically significant at 95% CI for MetS and all its components except for hypertriglyceridaemia (P=0.61). This is illustrated in table 2.

The prevalence of MetS was 73% (290) and was more common in women than in men (90.5% and 50% respectively, P< 0.001 at 95% CI). Figure 1 Shows that the prevalence of metabolic syndrome increased with age and peaked in the 60 – 69 age range**.**

Clustering of the MetS components were assessed using the NCEP ATP III as shown in table 3 above. The most common combination was abdominal obesity and hypertension (68% in women, 44% in men, P<0.001 at 95% CI) and the lowest was hypertriglyceridaemia and low HDL (11% in both men and women, P=0.89 at 95% CI). See table 3.

As shown in table 4, abdominal obesity measured by waist circumference alone had a sensitivity and specificity of 90% with positive and negative predictive values of 96% and 78% respectively. Even though hypertension had a high sensitivity, its specificity was relatively poor (56%).

It is also interesting to note that both hypertriglyceridaemia and low HDL had 100% specificity for MetS but had poor sensitivity (42% and 28% respectively).

Figure 2. Age Distribution of particapants with Metabolic Syndrome

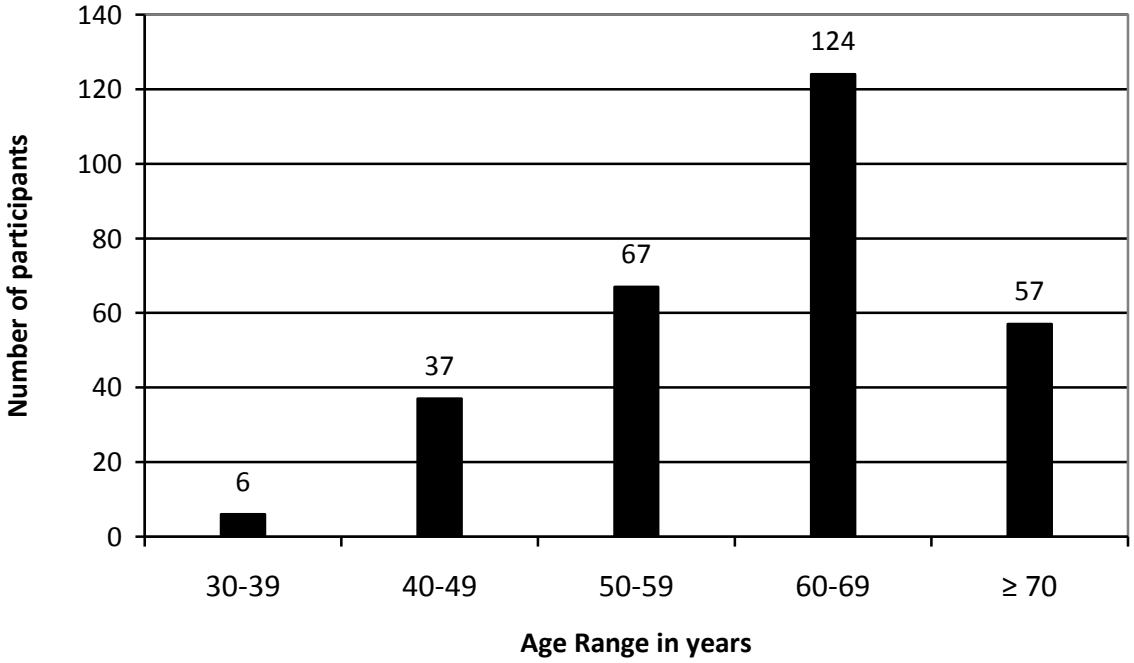


Table 3: Combination of different components of the MetS among type 2 DM patients by sex

	Total	Women	Men	P value
Abdominal obesity and hypertension	**248 (62)**	**169 (68)**	**79 (44)**	**<0.001†**
Abdominal obesity and Hypertriglyceridaemia	**95 (24)**	**59 (27)**	**36 (20)**	**0.138**
Abdominal obesity and low HDL	**59 (15)**	**43 (19)**	**16 (9)**	**0.004†**
Hypertension and Hypertriglyceridaemia	**107 (27)**	**70 (32)**	**37 (21)**	**0.016**
Hypertension and low HDL	**67 (17)**	**50 (23)**	**17 (10)**	**<0.001†**
Hypertriglyceridaemia and low HDL	**44 (11)**	**24 (11)**	**20 (11)**	**0.893**

All data are n (%)
†Difference between men and women statistically significant at 95% CI

Table 4 Diagnostic accuracy of waist circumference measurement alone in comparison with other MetS components

MetS component		Sensitivity	Specificity	Positive predictive value	Negative predictive value
Abdominal obesity (Large WC)	Total	90	90	96	78
	Male	92	91	91	92
	Female	90	86	98	47
Hypertension	Total	94	56	85	78
	Male	93	62	71	90
	Female	95	33	93	39
Hypertriglyceridaemia	Total	42	96	97	38
	Male	48	96	92	65
	Female	38	100	100	15
Low HDL	Total	28	98	98	33
	Male	26	98	92	57
	Female	28	100	100	13
High BMI	Total	56	80	88	40
	Male	62	84	80	69
	Female	52	57	92	11

All data are percentages

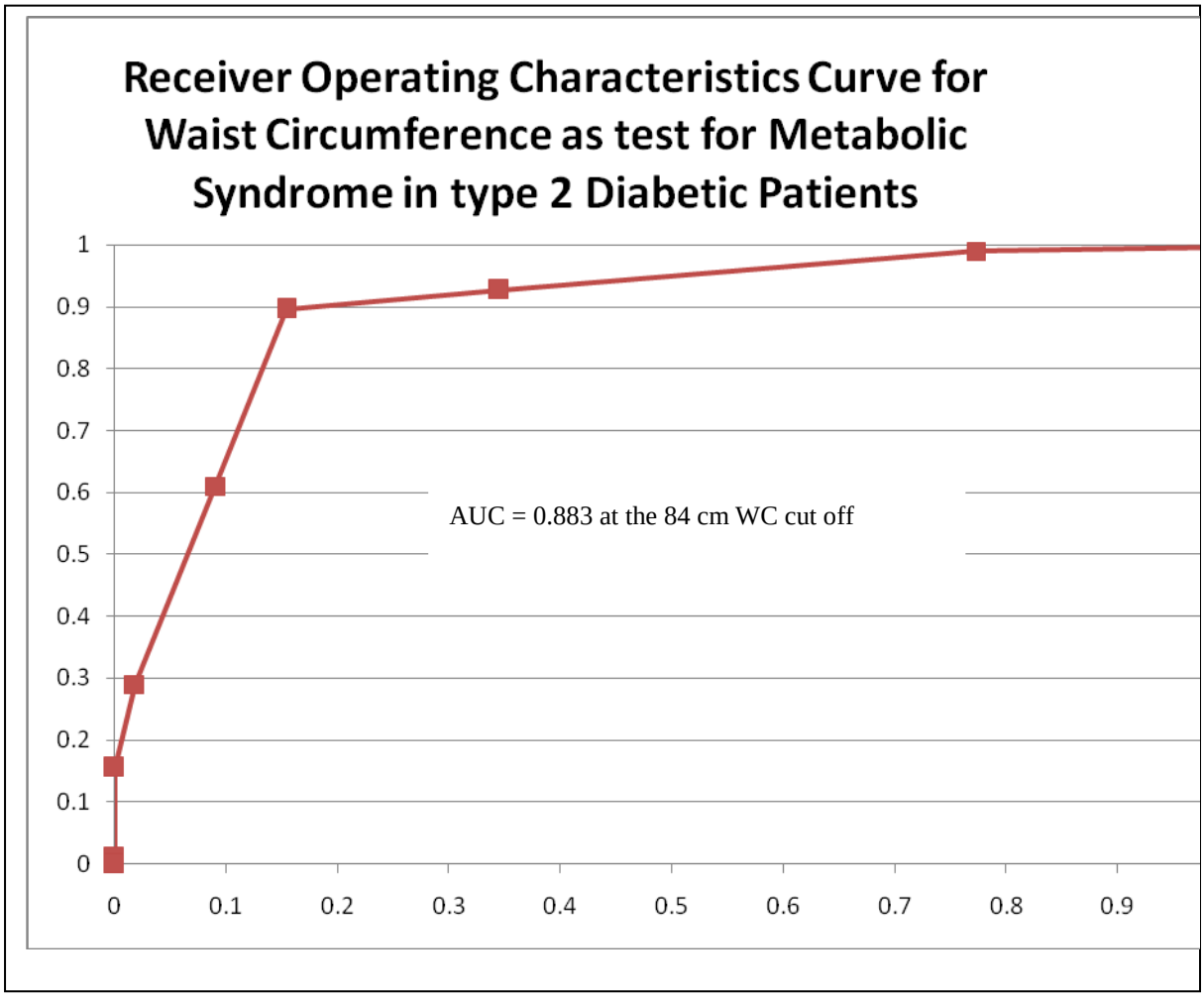


Figure 3 A graph of waist circumference sensitivity in the y axis against 1-specificity in the x axis.

The diagnostic accuracy of waist circumference alone was relatively good (AUC= 0.883) and was optimum at the 84cm cut off.

CHAPTER 6

6.0 DISCUSSION

This study was conducted to determine the diagnostic accuracy of waist circumference measurement alone for MetS and to determine the prevalence of the syndrome among type 2 DM patients.

The MetS is the clustering of cardiovascular risk factors such as type 2 DM, obesity, hypertension and dyslipidaemia in an individual. Risk factors of MetS include type 2 DM, obesity, aging and sedentary lifestyle [18,19] and it is estimated that most patients (~75%) with type 2 DM have the MetS [1]. This study reports a similar prevalence of 73% for MetS. The prevalence of MetS was higher in women and increased with age. These findings are similar to other studies done around the world [2,16,20]. In this report, the prevalence of MetS peaked in the 60 to 69 years age range. These findings are similar to those reported in a Nigerian study [2] but different from other studies done in Nigeria [9] and Seychelles [21] that reported highest prevalence in the 70-79 and 45-54 age brackets, respectively.

The prevalence of the MetS components is variable across populations. Hypertension and abdominal obesity were the most prevalent components of metabolic syndrome. This finding was similar to the Seychelles study [21] but different from the Nigerian study [9] which instead documented abdominal obesity and low HDL as the most prevalent components. Hypertension was found in 80% of the study subjects and like abdominal obesity, it was more common in females than males. This gender difference is similar to reports from South Africa [16], China [22] and Nigeria [9].

Even though the exact cause of the MetS is not known, abdominal obesity is believed to play a central role in its development and appears to precede the appearance of the other MetS components [1,9,12,17]. A study in Cameroon [12] has even suggested that the prevalence of MetS in sub Sahara Africa may be driven by abdominal obesity which is diagnosed by simple waist circumference measurement. Waist circumference measurement is an important component of the most recent and frequently used diagnostic criteria (NCEP ATP III) for the MetS, and even though its diagnostic accuracy for insulin resistance has been studied before [23], to the best of my knowledge its diagnostic accuracy for MetS as defined by the NCEP ATP III criteria was not assessed in previous studies. This study reports a relatively high

sensitivity and specificity of 90% and positive and negative predictive values of 96% and 78% respectively. This finding is not strange with the observation that abdominal obesity plays a central role in the development of MetS and appears to precede the appearance of the other MetS components [1,9]. In addition, many studies have reported a closer correlation of abdominal obesity with insulin resistance, dyslipidaemia, hypertension and arthrosclerosis than with obesity defined by BMI. Even though hypertension had a higher sensitivity (94%), its specificity was comparatively poor (56%). It is also worth noting that both low HDL and high serum triglycerides had 100% specificity in females but suffered relatively poor sensitivities (28% and 42% respectively).

Last but not the least, the diagnostic accuracy of waist circumference measurement alone was relatively good as assed by area under the receiver characteristic curve for different cut offs of waist circumference and it was optimum at the 84cm cut off (AUC=0.883).

6.1 STUDY LIMMITATIONS

Even though the study was conducted relatively successfully and met its objectives, it had the following limitations.

Firstly, we were not able to assess the prevalence of MetS and the diagnostic accuracy of waist circumference for MetS in non diabetic patients and in the general population (outside UTH) due to funding limitations. Therefore, study results may not apply to non diabetic patients.

Secondly, type 2 DM patients who had just come to make appointments in the morning were included in the study so as to increase the number of enrolments. This might have affected the study findings.

Last but not the least, other existing diagnostic criteria such as the IDF and WHO were not assessed and results using these criteria could have yielded different results.

CHAPTER 7

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 Conclusions

This study has reported a high prevalence of MetS among patients with type 2 DM thereby predicting a high disease burden from possible cardiovascular complications.

The study has also found a relatively high diagnostic accuracy of waist circumference measurement alone for MetS. This implies that waist circumference measurement alone can be used as a simpler alternative for diagnosing metabolic syndrome among type 2 DM patients in resource limited countries such as Zambia.

6.2 Recommendations

1. There is need for all health care providers including those at the primary care level to screen all type 2 DM patients for MetS early enough to intervene and as such reduce the cost burden on our health system as it pertains to non communicable diseases.

2. In type 2 DM patients who cannot afford laboratory tests related to the existing diagnostic criteria for MetS, waist circumference measurement alone using the 84cm cut off for both sexes has been proposed as a reasonably tested alternative. This can aid early diagnosis and treatment of the MetS.

3. There is need to formulate evidence based clinical local guidelines for MetS that will incorporate the use of waist circumference measurement especially at the primary care level.

4. Further studies are needed in order to determine the prevalence of MetS in the Zambian general population and also to validate the use of waist circumference measurement in non diabetic patients in predicting MetS and putting into account the limitations encountered in this study.

REFERENCES

1. Fauci A.S, Braunwald E, Kasper D.L, Hauser S.L, Longo D.L, Jameson J.L *et al* HARRISON'S principles of INTERNAL MEDICINE.2008. 17th Edition. McGraw-Hill. 1509-14.

2. Adediran O.S, Edo AE, Jimoh A.K, Ohwovoriole A.E. Prevalence of Metabolic Syndrome among Nigerians with type 2 diabetes. *Diabetes International, African Edition 2007; 15(1): 13-14.*

3. Mathew GK, Praveen A. MEDICINE-Prep' Manual for Undergraduates. 2008. 3rd Edition. 747-8.

4. Onyemelukwe G.C, Bakari A.G. The Metabolic Syndrome among Nigerians with type 2 Diabetes. *MERA. 2006; 26:21-23*.

5. Philip J, Neville R, Rachael L. The obesity epidemic, Metabolic Syndrome and future prevention strategies. *European journal of cardiovascular prevention and rehabilitation.2004; 11:3-8*

6. Reaven G: Metabolic Syndrome: Pathophysiology and Implications for Management of Cardiovascular diseases. *Circulation* 2002, 106:286-288.

7. Chaiken R.L, Barneji M.A, Huey H, Lebovitz H.E. Do blacks with NIDDM have an insulin resistance syndrome? *Diabetes 1993; 42: 444-9.*

8. World Health Organization. Prevention of Diabetes Mellitus. *Technical Report Seriesno. 844. WHO, Geneva, 1994*

9. Anthonia O. Prevalence and gender distribution of Metabolic Syndrome. *Diabetology and Metabolic Syndrome.2010; 2:1.*

10. Stern M, Gonzalez-Villalpando C, Williams K. Does the Metabolic Syndrome improve identification of individuals at risk of type 2 Diabetes Mellitus and or cardiovascular disease? *Diabetes Care 2004; 27(11):2676-81.*

11. Chinenye S, Unachuku C.N, Hart A. Diet and diabetes: theory and practice for care providers. *Diabetes International 2007; 15 (1):9-11*

12. Fezeu L, Balkau B, Kengne A.P, Sobyngwi E, Mbanya J.C: Metabolic Syndrome in a sub-Saharan African setting: central obesity may be the key determinant. *Atherosclerosis 2007, 193(1): 70-76.*

13. Jorge E, Herman S, Beatriz C, Honorio S, Carlos P.B. Prevalence of Metabolic Syndrome in Latin America and its association with subclinical carotid atherosclerosis: the CARMELA cross sectional study. *Cardiovascular & Diabetology 2009; 8:52*

14. Mansour A.A. Prevalence of Metabolic Syndrome among patients with type2 Diabetes in Iraq. *MERA 2007; 29:12*

15. Akbar D.H. Metabolic Syndrome X is common in Saudi type2 Diabetic patients. *Diabetes International 2002; 12: 47-9.*

16. Kalk W.J, Joffe B.I. The Metabolic Syndrome, insulin resistance, and its surrogates in African and white subjects with type 2 Diabetes in South Africa. *Metab Syndr Relat Disord, winter* 2008*; 6(4): 247-55.*

17. National Institutes of Health. Third report of the National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III). *Bethesda: NHI, 2001*.

18. Lara-Castro C, Fu Y, Chung B.H, Garvey W.T: Adiponectin and the Metabolic Syndrome: mechanisms mediating risk for metabolic and cardiovascular disease. *Curr Opin Lipidol* 2007, **18**(3)**:** 263-70.

19. Renaldi O, Pramono B, Sinorita H, Purnomo L.B, Asdie RH, Asdie A.H: "Hypoadiponectinemia: a risk factor for Metabolic Syndrome". *Acta Med Indones* 2009, **41**(1)**:** 20-4.

20. Pirjo I, Johan E, Jaana L, Helena H, Sirkka K, Mauri L et al.: Prevalence of the Metabolic Syndrome and Its Components Findings from a Finnish general population sample and the Diabetes Prevention Study cohort. *Diabetes Care 2004, 27(9): 2135-2140*

21. Kelliny C, William J, Riesen W, Paccaud F, Bovet P. Metabolic syndrome according to different definitions in a rapidly developing country of the African region.*Cardiovascular Diabetology 2008, 7: 2.*

22. He Y, Jiang B, Wang J: Prevalence of the Metabolic Syndrome and its relation to cardiovascular disease in an elderly Chinese population. *J Am Coll Cardiol* 2006, 47: 1588-94.

23. Justo S.J, Bruce D.J, Thomas G.A, Kent R.B, Gary L.S, Stephen T.T. Correspondence between the Adult Treatment Panel III Criteria for Metabolic Syndrome and Insulin Resistance. *Diabetes Care 2006, 29: 668-672.*

APPENDIX A

DATA COLLECTION SHEET

Sheet#.....Date.....

TITLE: Diagnostic accuracy of waist circumference in detecting Metabolic Syndrome in type 2 Diabetes Mellitus patients.

1. DEMOGRAPHIC DATA
    a. Age ____ ____
    b. Sex □male □ female
    c. Marital status □ single □married □divorced □widowed
    d. Race.....
2. HISTORY
    a. Duration of Diabetes.....
    b. Family history of Diabetes □Y □N
    c. Are you on medications for diabetes □Y □N
    d. If on medications for diabetes, type of diabetic drugs
        i. Daonil
        ii. Metformin
        iii. Insulin
        iv. Daonil and Metformin
        v. Others.....
    e. Are you Hypertensive□ Y/ □N
    f. If hypertensive duration of hypertension.....
    g. Are you on medications for hypertension □ Y/ □N
    h. If on medications for hypertension, type of drugs
        i. ACEI
        ii. CCB.
        iii. Diuretic
        iv. ACE/ARB and CCB
        v. □others.....
    i. History of heart attack □ Y/ □N
    J. History of stroke in the past□ Y/ □N
    K. History of amputation □Y□N

3 CLINICAL EXAMINATIONS

a. BP_____/_____mmHg
b. Height.....m
c. Weight.....kg
d. Waist circumference.....cm

4 LABORATORY RESULTS

a. Serum triglycerides.....mmol/l

b.Serum HDL.....mmol/l

b.FBS.....mmol/l

APPENDIX B

Informed Consent Form

Title: Diagnostic accuracy of waist circumference in detecting metabolic syndrome in type 2 diabetes mellitus patients

Site: clinic 5, UTH, Lusaka, Zambia.

Hello,

My name is Dr Humphrey Chanda a Registrar in Department of Medicine at the University Teaching Hospital and doing a research study for my Masters Degree.

Introduction

You are invited to consider participating in this research study. Your participation is voluntary and you are free to withdraw from the study at any time. It is important that you read and fully understand information on this leaflet as it will help you in making the decision. If unable to understand, an interpreter will be provided to help you go through the leaflet.

Purpose of the study

The human body has the heart, brain and the kidneys that perform very important functions for survival. These organs are affected by high levels of fat, high blood pressure, obesity and high sugar levels causing complications that lead to morbidity and mortality. The purpose of this study is to find out whether measuring waist circumference alone can help patients at risk of these complications

Procedures of the study

If you agree to participate in the study, information about your sex and age will be obtained. A physician will examine you and samples of blood will be collected from you to test for fats.

Possible risk factors are as follows:

Blood collection may cause pain at site of puncture.

Air embolism and infection are very rare complications that can occur after vein puncture. Qualified personnel will collect the blood samples to prevent such complications.

Benefits of the study

Benefits are that participants in this study will be screened for heart disease, hypertension, abnormal levels of fat and obesity and the findings will help in laying intervention strategies to prevent these complications

Financial arrangements

You will not be paid for participating in the study. There are no costs for any related study procedures.

Confidentiality

All information obtained during the course of this study will be kept strictly confidential. Your records will be given unique identification numbers and the initial identification details won't be used. All physical records will be kept in a locked locker with access limited to the research team. Electronic data will be password protected.

Source of Information

If you have any questions, concerns and clarifications, please contact the following:

Dr Humphrey Chanda, Department of Internal Medicine/Bag RW1X Lusaka phone 260977121123 or chairperson, UNZA Biomedical Research Ethics Committee, P.O. Box 50110, Lusaka Phone +2601256067

INFORMED CONSENT FORM

I.....having read and clearly understood the above written information, consent to taking part in this research study.

Participants signature or thumb print Date_____

Witness Date_____

APPENDIX C

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
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E-mail: unzarec@unza.zm

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

Assurance No. FWA00000338
IRB00001131 of IORG0000774

23 November, 2010
Our Ref: 014-08-10

Dr Humphrey Chanda, BScHB, MBChB
P/Bag RW1X
LUSAKA

Dear Dr Chanda,

RE: SUBMITTED RESEARCH PROPOSAL: **"PREVALENCE OF METABOLIC SYNDROME AND ITS DIAGNOSIS USING WAIST CIRCUMFERENCE MEASUREMENT ALONE, AMONG MEDICAL OUTPATIENTS AT UNIVERSITY TEACHING HOSPIAL, LUSAKA, ZAMBIA"**

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 8 September, 2010 where changes/clarifications were recommended. We would like to acknowledge receipt of the corrected version with clarifications. The proposal is approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).
- **Ensure that a final copy of the results is submitted to this Committee.**

Yours sincerely,

Dr E. M. Nkandu
CHAIRPERSON

Date of approval: 23 November, 2010 **Date of expiry**: 22 November, 2011