DISSERTATION SUBMITTED FOR THE MASTER'S DEGREE IN MEDICAL BIOCHEMISTRY

TITLE

UTILITY OF INDIAN DIABETIC RISK SCORE (IDRS) FOR SCREENING OF DIABETIC NEPHROPATHY IN TYPE 2 DIABETES MELLITUS PATIENTS AND CONTROL SUBJECTS

SUBMITTED

BY

TANMAY PAWASKAR

2023

DEPARTMENT OF BIOCHEMISTRY

INTEGRAL INSTITUTE OF MEDICAL SCIENCES AND RESEARCH

FACULTY OF HEALTH & MEDICAL SCIENCES

INTEGRAL UNIVERSITY

LUCKNOW-226026, U.P

INTEGRAL INSTITUTE OF MEDICAL SCIENCE AND RESEARCH INTEGRAL UNIVERSITY, LUCKNOW

TITLE

UTILITY OF INDIAN DIABETIC RISK SCORE (IDRS) FOR SCREENING OF DIABETIC NEPHROPATHY IN TYPE 2 DIABETES MELLITUS PATIENTS AND CONTROL SUBJECT

A

DISSERTATION

SUBMITTED

In partial fulfillment of the requirement for the award of degree of

Master of Science In
Medical Biochemistry By

TANMAY PAWASKAR

Enrollment Number- 2000102846

SUPERVISOR

Dr. Mohd. Mustufa Khan
HOD. Basic Medical Sciences
IIMS&R, Lucknow(U. P.)

CO-SUPERVISOR

Dr. Mukhtar Ahmad
Department of medicine,
IIMS&R, Lucknow(U. P.)

DEPARTMENT OF BIOCHEMISTRY
INTEGRAL INSTITUTE O F MEDICAL SCIENCES AND RESEARCH

DEPARTMENT OF BIOCHEMISTRY
Integral Institute of Medical Sciences
& Research
Dasauli, Kursi Road, Lucknow-226026

CERTIFICATE

This is to certify that **Tanmay Pawaskar** student of **M.Sc. Medical biochemistry**. Integral University has completed his dissertation entitled "**Utility of Indian diabetic risk score (IDRS) for screening of diabetic nephropathy in type 2 diabetes mellitus patient and control subject**" successfully. He has completed this work in the Department of Biochemistry, Integral Institute of Medical Sciences and Research, Integral University under the guidance of **Dr. Mohammad Mustufa Khan**. The dissertation was a compulsory part of his M.Sc. degree.

I wish him good luck and a bright future.

Dr. Roshan Alam
Professor& Head
Department of Biochemistry
IIMS&R, Lucknow

DEPARTMENT OF BIOCHEMISTRY
Integral Institute of Medical Sciences & Research
Dasauli, Kursi Road, Lucknow-226026

CERTIFICATE

This is to certify that **Tanmay Pawaskar** student of **M.Sc. Medical biochemistry**. Integral University has completed his dissertation entitled "**Utility of Indian diabetic risk score (IDRS) for screening of diabetic nephropathy in type 2 diabetes mellitus patient and control subject**" successfully. He has completed this work in the Department of Biochemistry, Integral Institute of Medical Sciences and Research, Integral University under the guidance of **Dr. Mohammad Mustufa Khan**. The dissertation was a compulsory part of his M.Sc. degree.

I wish him good luck and a bright future.

Supervisor:

Dr. Mohammad Mustufa Khan
HOD. Basic Medical Sciences
IIMS&R, Lucknow (U.P)

DEPARTMENT OF BIOCHEMISTRY
Integral Institute of Medical Sciences
& Research
Dasauli, Kursi Road, Lucknow-226026

COPYRIGHT

Declaration by the candidate

I hereby declare that Integral Institute of Medical Sciences & Research, Integral University, Lucknow shall have the right to preserve, use and disseminate this dissertation in print / electronic format for academic/research purposes.

I will publish the research paper related to my dissertation only with the consent of my guide.

Date:

Place: Lucknow **Tanmay Pawaskar**

ACKNOWLEDGEMENT

The success and outcome of this dissertation required a lot of guidance and assistance from many people and I am extremely privileged to have gotten this all along the completion of my dissertation. All that I have done is only due to such supervision and assistance and I would not forget to thank them.

I place on record, my sincere thank you to ***Prof. (Dr.) Abha Chandra,*** *Dean, IIMS&R, for her support and encouragement.*

Firstly, I would like to acknowledge. ***Dr. RoshanAlam****, Professor, and Head of the Department of Biochemistry, Integral Institute of Medical Sciences and Research, Integral University, Lucknow, for his continuous guidance and valuable suggestions enabled me to overcome various difficulties and complete my thesis.*

I owe my deep gratitude to my supervisor. ***Dr. Mohammad Mustufa Khan****, Head of Basic Medical Sciences, Integral Institute of Medical Sciences and Research, Integral University, Lucknow, ploughed through several preliminary versions of my text, making critical suggestions and giving untiring help. His expertise, invaluable guidance, constant encouragement, affectionate attitude, understanding, patience, and healthy criticism added considerably to my experience. His technical and editorial advice was essential to the completion of this dissertation and has taught me innumerable lessons and insights on the workings of academic research in general. Without his continual inspiration, it would have not been possible to complete this study.*

I am highly grateful to my Co - supervisor ***Dr.*****Mukhtar Ahmad****, Assistant Professor Department of Medicine. Integral Institute of Medical Sciences and Research, Integral*

University.Lucknow, for his constant encouragement and providing all the necessary facilities for the research work.

I am deeply obliged and grateful to ***Dr. PriyankaThapa****, Assistant Professor, and* ***Dr. SabaKhan*** *Assistant Professor Department of biochemistry for their immense support and guidance.*

My cordial and sincere thanks to all my non-teaching staff for giving me valuable academic suggestions, encouragement, and reliable help during my academic course.

I would also like to thank my lab members who have played an important role in my research.

I am thankful to all my friends ***Sudhakar Singh, Ankitaverma, Arnold Ratemo****and* ***RichaAwasthi****who were always there to help me in any kind of situation helped me all around the year and with their wishes for providing me moral support and timely help, whenever I was in need I was able to overcome every barrier that stood in the achievement of my thesis work.*

Date:

Place ***TanmayPawaskar***

CONTENTS

List of Abbreviations

UA	Uric Acid
SUA	Serum Uric Acid
S.Cr	Serum Creatinine
T2DM	Type 2 Diabetes Mellitus
IDRS	Indian Diabetes Risk Score
ADA	American Diabetes Association
ESRD	End Stage Renal Disease
CKD	Chronic Kidney Disease
DKD	Diabetic Kidney Disease
ESKD	End stage kidney disease
BMI	Body mass index

SYMBOLS

Mg	Milligram
Dl	Deciliter
Cm	centimetre
Kg	Kilogram
mmol/l	Millimoles per liter
mm/Hg	Millimeter of Mercury
kg/m^2	Kilogram per meter square
%	Percentage
Lt	Litre
≥	Greater than or Equal

INTRODUCTION

INTRODUCTION

Indian Diabetes Risk Score (IDRS) risk ratings, developed recently to identify high risk patients, are based on basic anthropometric and demographic characteristics (Dudeja et al, 2017). By using of IDRS, a public health worker may screen the high risk population, which is a straightforward instrument. IDRS was developed using the country's largest population-based study on diabetes (Dudeja et al, 2017). Age, physical activity, and waist circumference, three of the characteristics, are risk factors for both metabolic syndrome and cardiovascular disease, suggesting that the IDRS may be a reliable predictor of both conditions. Huang et al (2009) reported that age and a family history of diabetes are two risk factors that cannot be changed, whereas waist size and physical inactivity can be. Modifying the modifiable risk variables, in accordance with the Indian Diabetes Risk Score, can drastically lower the risk score. Regardless of their blood sugar levels, subjects with a high IDRS are excellent candidates for lifestyle changes because they are risk factors for both type 2 diabetes mellitus (T2DM) and cardiovascular disease (CVD) (Gupta et al, 2009).

An elusive public health issue is diabetes. It has become a 21st-century global pandemic (Acharya et al, 2020). According to the International Diabetes Federation (IDF), presently 540 million of people have diabetes worldwide (2021). It was further reported that prevalence of diabetes is 10.5% worldwide (IDF, 2021). Kumar et al (2023) reviewed that prevalence of diabetes is 9.6% in India (Kumar et al, 2023). One of the world's largest diabetic populations is found in India. The issue is made worse by the fact that around 66% of diabetes in India go undiagnosed. This demonstrates the necessity of developing efficient screening methods to reveal the disease's hidden burden (Joshi et al, 2005).

Although ketoacidosis seldom occurs on its own, it may occur under stress brought on by another condition, such as an infection. When type 2 diabetes first manifests, obesity is typically present, and it makes insulin resistance worse.Type 2 diabetes usually stays untreated for many years since it gradually develops and does not initially show the typical signs of diabetes.Despite this, Although they may have normal or high circulating insulin levels, their insulin resistance prevents them from keeping blood glucose levels within the normal range. They therefore exhibit relative, not absolute, insulinopenia. With weight loss or medication, insulin resistance may improve, resulting in normalization of blood sugar levels (Lin CH et al, 2016).

Weight gain, ankle and leg swelling, frequent nightly urination, morning sickness, anaemia, and high blood pressure are all indicators of kidney damage in diabetic patients. Albuminuria, or the excretion of albumin in the urine, is another sign and symptom. 30% of patients with type 1

diabetes and 40% of those with T2DM develop Diabetic kidney disease, respectively. Diabetes is the leading cause of Diabetic kidney disease (DKD) and End-stage renal disease (ESRD) (Hussain et al, 2021).

The rise of the economy was accompanied by an increase in diabetes prevalence. Diabetes is now widely prevalent in India, where it has reached 9% of the population overall and 20% in some of the wealthier southern towns. According to the IDF, India will have 100 million diabetics by 2030 (Pradeepa et al, 2021). Early detection of those who are at high risk would make it easier to implement suitable dietary changes and increased physical exercise, delaying or perhaps preventing the onset of diabetes. This means that identifying those who are at risk is crucial if we are to stop diabetes in India (Galaviz et al, 2015).

Diabetes has been dubbed the world's leading disease in India. Diabetes affects 19% of the population of the world in India (Gupta MK et al, 2022). By 2030, 80 million more people are predicted to suffer from T2DM (Singh N et al, 2018). IDRS it was shown that rural areas have a higher ratio of undiagnosed to diagnosed diabetic mellitus than non-rural, or urban, areas (Mohan V et al, 2008). This underlines the need for early action to prevent problems and community-wide awareness for screening. In India, the incidence of T2DM is higher in urban regions than in rural onesand it was discovered that the prevalence of pre-diabetes (14.5% in urban areas and 14.7% rural regions) was nearly comparable (Anjana RM et al, 2011).

Based on the Asian Indian phenotype, it was determined that Asian Indians were more likely to have a bigger waist circumference, a lower body mass index (BMI), and more abdominal adiposity, making them more prone to T2DM and the diseases associated with diabetic nephropathy (DN) (Mohan V et al, 2007).

REVIEW OF LITERATURE

REVIEW OF LITERATURE

ESRD is most commonly brought on by DKD an extremely harmful side effect of diabetes. An analysis predicted that China has an estimated 113.9 million diabetics (Iseki k et al,2003). Extrapolations from cross-sectional research have revealed that up to 60% of Asian patients experience micro- or macroalbuminuria, and it's probable that 68 million Chinese people with diabetes also have DKD (Xu Y et al, 2013) which would put a significant strain on the healthcare system. Early detection and treatment of DKD may lessen exposure to chronic renal disease and postpone or prevent ESRD. A risk score was developed without the requirement for a laboratory test as a step-by-step screening tool for undetected type 2 diabetes and has proven to be efficient and economical (Li P et al, 2015).

This crucial understanding made it possible for medical professionals to identify diabetic nephropathy considerably sooner than they had previously, allowing for earlier treatment approaches to stop the disease's progression. Microalbuminuria is the accumulation of 30 to 300 mg of albumin in the urine per 24 hours. Proteinuria or overt nephropathy is terms used to describe the condition when albumin levels are higher than 300 mg per 24 hours. Microalbuminuria has been referred to as "early diabetic nephropathy" or "incipient nephropathy," which to some signifies a young, maybe inconsequential disease that doesn't need treatment. But it must be emphasized that the earliest marker we are aware of is microalbuminuria. It is clear that the molecular alterations that have taken place over time in the kidney's glomeruli are what are causing albumin to now be produced in the urine (Roshan et al, 2013).

The wealthy urban class's living habits are primarily to blame for this. Furthermore, their susceptibility is made worse by their ignorance of the importance of exercise, a balanced diet, and nutrition. Due to urbanisation and globalisation, there is a rise in the intake of high-fat, high-salt, and high-sugar (HFSS) meals. Many research studies among the urban population in India have been undertaken, but very few of them focused on the people who live in urban slums (Lyer SR et al, 2001). Certain gene mutations, such as those in the glucokinase or hepatic nuclear factor genes that cause juvenile or early-onset diabetes, can be identified in some families and are highly connected with specific types of diabetes (Almond et al, 2001).

ESRD is mostly brought on by DN, and it is predicted that 20% of T2DM people will develop ESRD at some point in their lifespan (Gheith el at, 2015). Clinically, the evolution of urine albumin excretion in diabetic kidney disease is typified by increasing rates of excretion from normoalbuminuria to microalbuminuria and finally end-stage renal disease. The first clinically discernible stage of diabetic kidney disease is microalbuminuria, at which time effective therapies can slow or stop the disease's progression. (Weir M R et al, 2004).

DKD is a serious condition that impacts between 20 and 40 percent of people with diabetes. Diabetic renal disease is the main cause of end-stage kidney damage in the West. Both people with T1DM and T2DM can develop DN, but T2DM patients are less likely to move on to ESRD. These patients account for over fifty per cent of all diabetics having hemodialysis because type 2 diabetes is more prevalent (Alicic et al, 2017). Each year, there are more cases of DKD contributing to ESRD.Increased excretion of urine albumin or decreased glomerular filtration rate (GFR), or both, are signs of DKD, according to clinical care and epidemiological investigations.The frequency of diabetes has risen to epidemic levels worldwide. Over 550 million people are expected to have diabetes by the year 2035, up from the current projection of well than 8% of the world's population, or roughly more than 350 million people. More than 40% of persons with diabetes are predicted to develop CKD (Saeadi et al, 2019).

Patient with T2DM mellitus may frequently experience elevated blood sugar, cholesterol, and triglyceride levels for a prolonged length of time without showing any symptoms. Their diagnosis is really frequently postponed until the onset of complications or until the disease is accidentally discovered by a medical practitioner. Morbidity and early death stem from suboptimal management of diabetes and associated morbidities, insufficient health care facilities for early detection and beginning of therapy, and both. They experience several chronic problems that result in mortality and irreparable disability (Goyal et al,2022).

Symptoms

Patient would probably not experience any signs or symptoms of DN in its early stages. In later stages, signs and symptoms may include: deteriorating blood pressure, swelling of the hands, eyes, greater frequency and rate of urine, less insulin or diabetic medication is required, concerns with confusion or attention, and breathing challenges.

AIM & OBJECTIVES

AIM & OBJECTIVES

AIM:

To validate the utility of Indian Diabetes Risk Score for screening of diabetic nephropathy in Type 2 diabetes mellitus patients and control subjects.

OBJECTIVES:

1. To define parameters for the Indian Diabetes Risk Score in people with Type 2 diabetes who are also controls.
2. To determine the diabetic nephropathy parameters such levels of serum uric acid, serum creatinine and urine albumin excretion in Type 2 diabetes Mellitus patients and control subjects.
3. To find the correlation of Indian Diabetes Risk Score parameters with parameters of diabetic nephropathy parameters in Type 2 diabetes mellitus patients, if any.

MATERIAL AND METHODS

RESEARCH QUESTION:

Is there any significant difference between Indian diabetic risk score and parameters of diabetic nephropathy in type 2 diabetes mellitus patients?

NULL HYPOTHESIS (H0):

There is no significant association between Indian diabetic risk score and parameters of diabetic nephropathy in type 2 diabetes mellitus patients.

ALTERNATE HYPOTHESIS (H1):

There is a significant association between Indian diabetic risk score and parameters of diabetic nephropathy in type 2 diabetes mellitus patients

METHODOLOGY

MATERIAL AND METHODS

Type of study – Case-Control study
Place of study – Department of Biochemistry, IIMSR, Integral University, Lucknow
Duration of study – January to June 2023

Sampling Method – Non-probability, Purposive sampling.

SUBJECTS SELECTION-:

In this case-control study, a total of 60 subjects (30 subjects of T2DM patients and 30 subjects of age and gender-matched healthy controls) were enrolled from the OPD, Department of Medicine, Integral Institute of Medical Sciences & Research (IIMSR) based on inclusion and exclusion criteria. A detailed demographic, medical and family history was taken from each subject. Written informed consent was taken from each subject.

INCLUSION CRITERIA (CASES):

1. Diagnosed cases of type 2 diabetes mellitus.
2. Subjects within the age of 35 to 65 years.
3. T2DM (Disease duration diagnosed to 10 years only).
4. Patients who have agreed to sign the consent form.

EXCLUSION CRITERIA: (CASES)

1. Diabetes mellitus More than 10 years disease duration
2. Patients have history of any chronic disease such as cancer or infectious disease such as tuberculosis.

SELECTION OF CONTROLS:

1. Apparently healthy individuals.
2. Subjects within the age of 35 to 65 years.
3. Subject who have agreed to sign the consent form

SAMPLE SIZE ESTIMATION:

$$n = \frac{2\,(Z_{\alpha/2} + Z_{1-\beta})^2}{\left(\frac{\mu_1 - \mu_2}{\sigma}\right)^2} = \frac{2(1.96 + 0.84)^2}{\left(\frac{\Delta}{\sigma}\right)^2}$$

Sigma = standard deviation (taken from previous studies)

Z1-β = represent the desired power

Zα/2 = represent the desired level of statistical significance

Effect size (Δ) = 0.75 (Allen et al, 2011).

Then,

For 80% power, $Z_{1-\beta}$ = (0.84)

For 0.05 significance level, $Z_{\alpha/2}$=1.96

Put the value in formula

Then n = 28.4 ≈ 30

The study will include **30** cases and **30**controls

INDIAN DIABETES RISK SCORE (IDRS)

Indian Diabetes Risk Score was calculated based on the two modifiable risk factors; waist circumference (WC), physical activity and two non-modifiable risk factors; age and family history of diseases for each subject. On the basis of IDRS subjects were divided into three groups; at low risk (<30), at moderate risk (30-50), and at high risk (≥60) (Mohan et al 2005, Khan et al 2017).

Table 1: Indian Diabetes Risk Score	
Particulars	**Score**
Age (YEARS)	
<35	0
35-49	20
>50	30
Abdominal obesity	
Waist<80(female), <90(male)-normal	0
Waist>80-89(female),>90-99cm(male)	10
Waist>90CM(female),100cm(male)	20
Physical activity	
Exercise regular	0
Moderate work	20
Sedentary work	30
family history	
No family history	0
Either parent	10
Both parents	20

ANTHROPOMETRIC PARAMETERS

Body mass Index (BMI): Body mass index is calculated by dividing a person's weight in kilogrammes by their height in metres squared.

Waist circumference (WC): Beginning at the top of the hipbone, wrap the tape measure around our bodies at the level of the belly button and record the distance in centimetres (cm).

COLLECTION OF SAMPLES:

A total of 2 ml of venous blood was collected from the subjects under aseptic conditions in a plain vial. The blood sample was allowed to clot at room temperature for 15 minutes. The sample was then be centrifuged at 1000 rpm for 10 minutes to separate the serum (Masonet al., 1979). Collect urine during 24 hours or as a random midstream sample if the test cannot be carried out on the same day.

- 0.50 µl serum was used for estimation of serum creatinine.
- 0.50 µl serum was used for estimation of serum uric acid.
- 3 ml urine was used for estimation of urine albumin

LABORATORY INVESTIGATION:

1. Estimation of serum creatinine by colorimetric method using Erbachem 7 semi auto analyzer

Methodology- Jeffe's Method

Principle:

In an alkaline media, picric acid and creatinine combine to generate an orange-colored complex with the alkaline picrate. The intensity of the color formed during the set time is proportional to the amount of creatinine in the sample.(Bowers, et al,1980)

Creatinine + Alkaline Picrate ------► Orange Colored Complex

Procedure:

Pipette into a clean dry test tube labeled as Standard (S) and Test (T):

pipette	Standard	Test
Working reagent	1000 µl	1000 µl
standard	100 µl	--
test	--	100 µl

NORMAL REFERENCE VALUES

0,6 – 1.2 mg/dL in males

0.5 -1.1 mg/dL in females

2. Estimation of serum uric acid by using Erbachem 7 semi auto analyzer

Principle

Using uricase, uric acid is transformed into allantoin and hydrogen peroxide. The catalytic action of peroxidase causes the hydrogen peroxide to further combine with a phenolic molecule and 4 aminoantipyrine to produce a crimson quinoneimine dye complex. The amount of uric acid in the sample directly correlates to the intensity of color formation (Henry R.J et al,1974).

Methodology - Modified Trinder method

Procedure

Pipette	Blank	Standard	Test
working reagent	1000 µl	1000 µl	1000 µl
Distilled water	20 µl	--	--
standard	--	20 µl	--
test	--	--	20 µl

Mix well and incubate for 5 minutes at 37^0C. Read the absorbance of standard and each test at 505 nm (500-540 nm) or 505/670 nm on bichromatic analyzer against reagent blank.(Henry R.J et al,1974)

NORMAL REFERENCE VALUES

2.5 -6.0 mg/dL in women

3.4 -7.0mg/dL in males

3. Estimation of urine albumin by using Erbachem 7 semi auto analyzer

Principle:

Microalbuminuria is an agglutination reaction-based turbidimetric immunoassay for the detection of albumin in urine. The activation buffer, Microalbuminuria anti-human antibody solution, and test material are combined, and the mixture is then left to react. When albumin is present, it creates an insoluble compound that results in turbidity, which is measured at 546 nm in wavelength. The amount of albumin present in the test material is shown by the turbidity that results.

Methodology: -Immunoturbidimetry method

PROCEDURE:

	FOR CALIBRATION	FOR SAMPLE
R1	450 UL	450 UL
R2	50 UL	50 UL
mix well and incubate for 5 min		
CALIBRATOR	10 UL	
SAMPLE		10 UL
mix well and read absorbance		

STATISTICAL ANALYSIS

Statistical analysis was performed using GraphPad and SPSS version 20.0. All the data was expressed as mean ± standard deviation. An unpaired t-test was performed to compare the study parameters between cases and controls. Pearson's correlation analysis was employed to determine the relationship between variables. A p-value <0.05 was considered statistically significant

OBSERVATION

&

RESULTS

RESULTS

In this case control study, 60% of cases and 80% of controls was found between the age-group of 35 to 49 years. In addition, 40% of cases and 20% of controls was found the age-group more than 50 years. In addition, it was found that 63% of cases and 30% of controls have abdominal obesity. In this addition, 73% of cases and 46% of controls were found physically inactive. Further, it was found that 16% of cases and 16% of control have a family history of diabetes, shown in **Table 2.**

Table 2: Distribution of case and control as per IRDS

Particulars	**Score**	**Case N (%)**	**Control N (%)**
Age (YEARS)			
<35	0	0 (0%)	0(0%)
35-49	20	18(60%)	24(80%)
>50	30	12(40%)	6(20%)
Abdominal obesity			
Waist<80(female), <90(male)-normal	0	4(13%)	10(33%)
Waist>80-89(female),>90-99cm(male)	10	7(23%)	11(36%)
Waist>90CM(female),100cm(male)	20	19(63%)	9(30%)
Physical activity			
Exercise regular	0	5(16%)	10(33%)
Moderate work	20	3(10%)	6(20%)
Sedentary work	30	22(73%)	14(46%)
family history			
No family history	0	25(83%)	25(83%)
Either parent	10	4(13%)	0(0%)
Both parents	20	1(3%)	5(16%)

On the basis of IDRS subjects were further grouped in at low risk (<30), at moderate risk (30-50), and at high risk (≥60). Results shown that 10% controls were at low risk, 18% controls were at moderate risk, and 33% controls were at high risk. Similarly, it was found that 13% cases were at moderate risk, and 36% cases were at high risk, shown in **Table 3.**

Table 3: IDRS Distribution			
IDRS	**At Low Risk (<30) N (%)**	**At Moderate Risk (30-50) N (%)**	**At High Risk (≥60) N (%)**
CONTROL	6(10%)	11(18%)	13(33%)
CASE	0(0%)	8(13%)	22(36%)
TOTAL	6(10%)	19(31%)	35(58%)

Mean of RBS, serum creatinine, serum uric acid, urine microalbumin, waist circumference and BMI was significantly elevated in cases compared to controls ($p<0.001$, $p<0.001$, $p=0.02$, $p<0.001$, $p=0.004$, $p=0.01$, respectively), shown in **Table 4.**

Table 4:Baseline characteristics of cases and controls

Parameters	**Cases (Mean ± SD) (n= 30)**	**Controls (Mean ± SD) (n= 30)**	**P value**
Age (years)	47.40±9.61	42.97±8.49	0.06
RBS (mg/dL)	290.20±70.04	143.53±29.78	<0.001*
SCr (mg/dL)	1.61±0.34	0.94±0.15	<0.001*
SUA (mg/dL)	5.47±1.21	4.73±1.15	0.02*
Urine Microalbumin (mg/dL)	120.18±32.25	15.15±4.39	<0.001*
Waist Circumference (cm)	95.70±14.10	86.37±9.90	0.004*
BMI (kg/m^2)	26.59±3.36	24.03±3.98	0.01*

Data represented as Mean ±SD.
**P value < 0.05, considered as statistically significant.*
BMI: Body mass index, RBS: Random blood sugar, SCr: Serum creatinine, SUA: Serum uric acid

Based on the IDRS, biochemical parameters were analyzed. Mean of RBS, serum creatinine, serum acid, urine microalbumin, waist circumference, and BMI gradual increased from low risk to moderate risk to high risk in controls. Mean of waist circumference was found significant difference between low risk to moderate risk to high risk in controls ($p < 0.001$), shown in **Table 5.**

Table 5: Biochemical parameters among controls as per IDRS

Parameters	**6(10%) (IDRS <30)**	**11(18%) (IDRS =30-50)**	**13(33%) (IDRS ≥60)**	**P <0.05**
Age (years)	36.67±2.87	46.91±11.29	42.54±4.78	0.045*
RBS (mg/dL)	139.17±30.20	136.82±25.89	151.23±30.85	0.45
SCr (mg/dL)	1.00±0.13	0.93±0.15	0.93±0.16	0.60
SUA (mg/dL)	4.10±0.55	4.75±1.15	5.01±1.23	0.26
Urine Microalbumin(mg/dL)	14.10±3.210	15.46±3.92	15.38±5.14	0.81
Waist Circumference (cm)	72.17±6.64	85.55±7.97	93.62±2.47	<0.001**
BMI (kg/m^2)	23.65±3.57	23.57±2.74	24.58±4.88	0.79

***Correlation is significant at the 0.01 level (2-tailed).*
**Correlation is significant at the 0.05 level (2-tailed).*
BMI: Body mass index, RBS: Random blood sugar, SCr: Serum creatinine, SUA: Serum uric acid

Based on the IDRS, biochemical parameters were analyzed. Mean of RBS, serum creatinine, serum acid, waist circumference, and BMI gradual increased from moderate to high risk in cases. Mean of waist circumference was found significant difference between moderate risk to high risk in cases (p <0.001), shown in **Table 6.**

Table 6: Biochemical parameters among cases as per IDRS

Parameters	**0(0%) (IDRS <30)**	**8(13%) (IDRS =30-50**	**22(36%) (IDRS ≥60)**	**P <0.05**
Age (years)	-	48.38±11.22	47.05±8.93	0.74
RBS (mg/dL)	-	267.38±30.96	298.50±77.9	0.29
SCr (mg/dL)	-	1.46±0.33	1.67±0.33	0.13
SUA (mg/dL)	-	4.98±0.99	5.65±1.23	0.18
Urine Microalbumin(mg/dL)	-	122.54±31.14	119.33±32.6	0.81
Waist Circumference (cm)	-	78.75±13.13	101.86±8.12	<0.001**
BMI (kg/m^2)	-	24.74±2.46	27.26±3.39	0.07

***Correlation is significant at the 0.01 level (2-tailed).*
**Correlation is significant at the 0.05 level (2-tailed).*
BMI: Body mass index, IDRS: Indian diabetes risk score,RBS: Random blood sugar, SCr: Serum creatinine, SUA: Serum uric acid

Correlation analysis among controls indicated that serum uric acid has shown a significant positive correlation with waist circumference and BMI among controls ($r = 0.366$, $p < 0.05$, $r = 0.501$, $p < 0.01$, respectively). IDRS has shown a significant positive correlation with waist circumference ($r = 0.845$, $p < 0.01$), shown in **Table 7, Figure 1, Figure 2, and Figure 3.**

Table 7: Correlations analysis among controls

	Age (years)	RBS (mg/dL)	SCr (mg/dL)	SUA (mg/dL)	UAE (mg/dL)	WC (cm)	BMI (kg/m^2)	IDRS
Age (years)	1	-0.083	-0.096	0.067	-0.248	-0.028	0.158	0.010
RBS (mg/dL)		1	-0.202	-0.098	-0.269	0.296	0.238	0.262
SCr (mg/dL)			1	0.054	-0.134	-0.233	0.268	-0.248
SUA(mg/dL)				1	0.229	**0.366***	**0.501****	0.227
UAE(mg/dL)					1	0.228	0.068	0.113
WC (cm)						1	0.089	**0.845****
BMI (kg/m^2)							1	-0.034
IDRS								1

**. Correlation is significant at the 0.05 level (2-tailed).*

***. Correlation is significant at the 0.01 level (2-tailed).*

BMI: Body mass index, IDRS: Indian diabetes risk score, SCr: Serum creatinine, SUA: Serum uric acid, UAE: Urinary albumin excretion, WC: Waist circumference

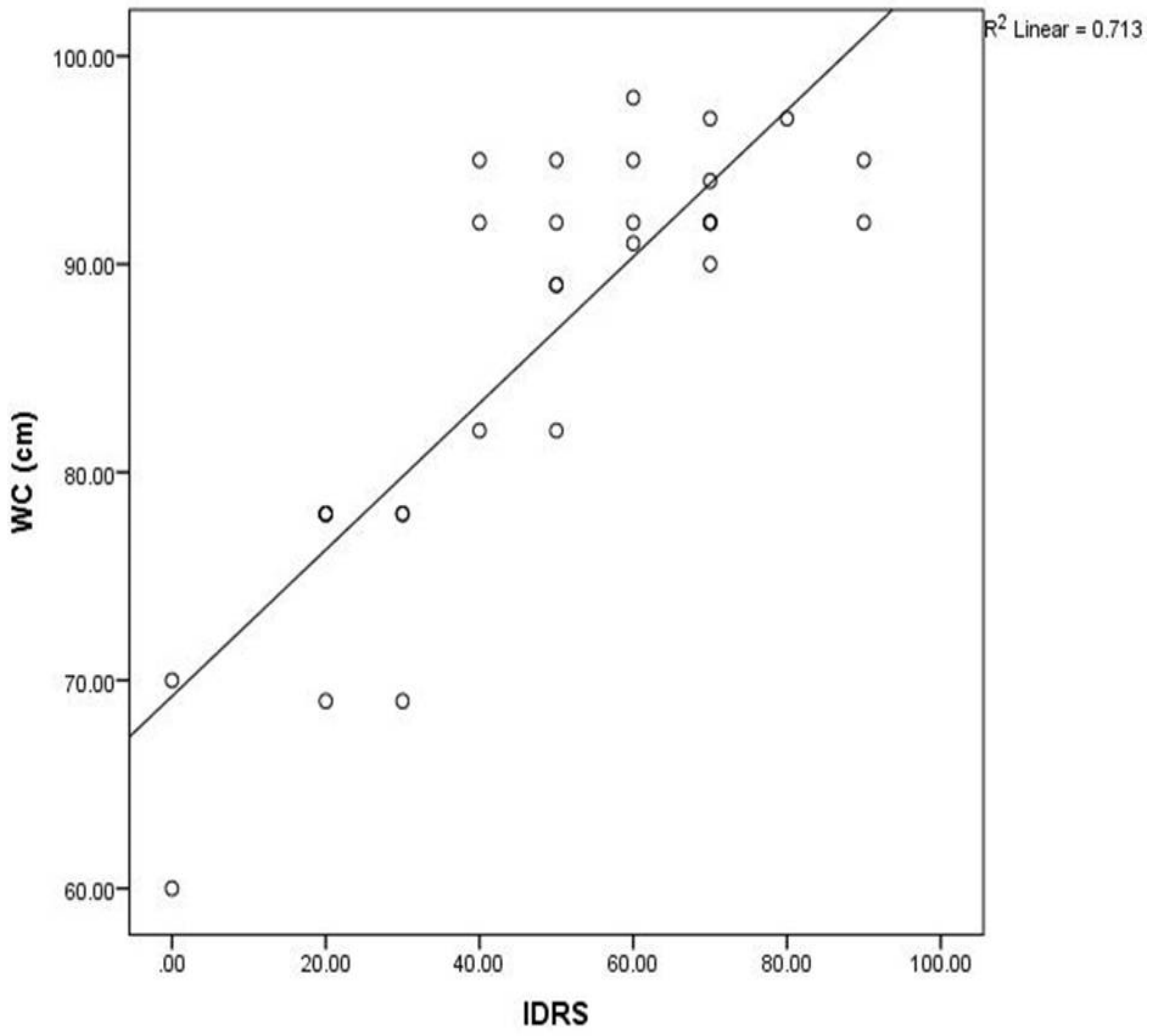


Figure 1: Relationship between waist circumference and IDRS among controls.

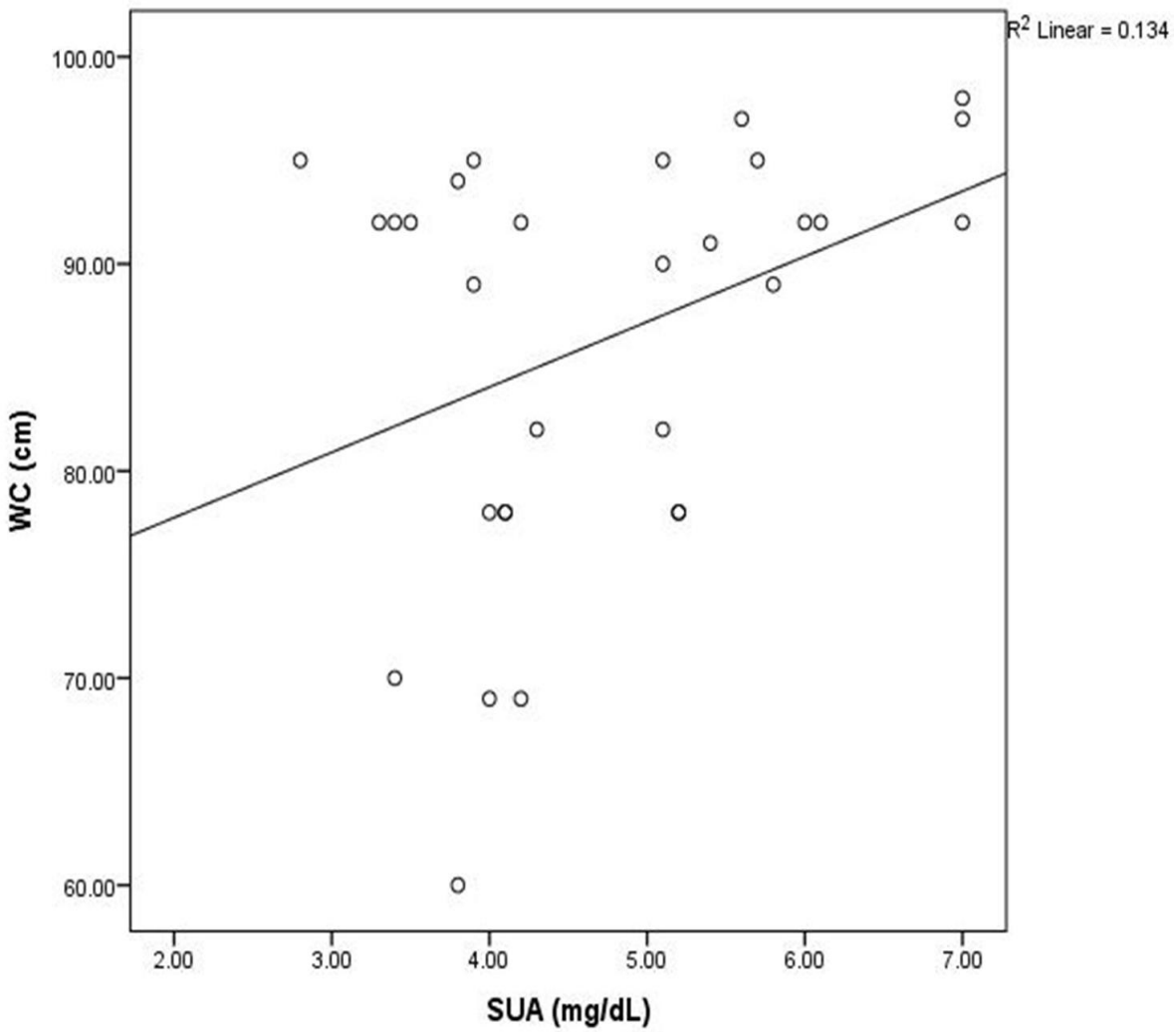


Figure 2: Relationship between waist circumference and serum uric acid among controls.

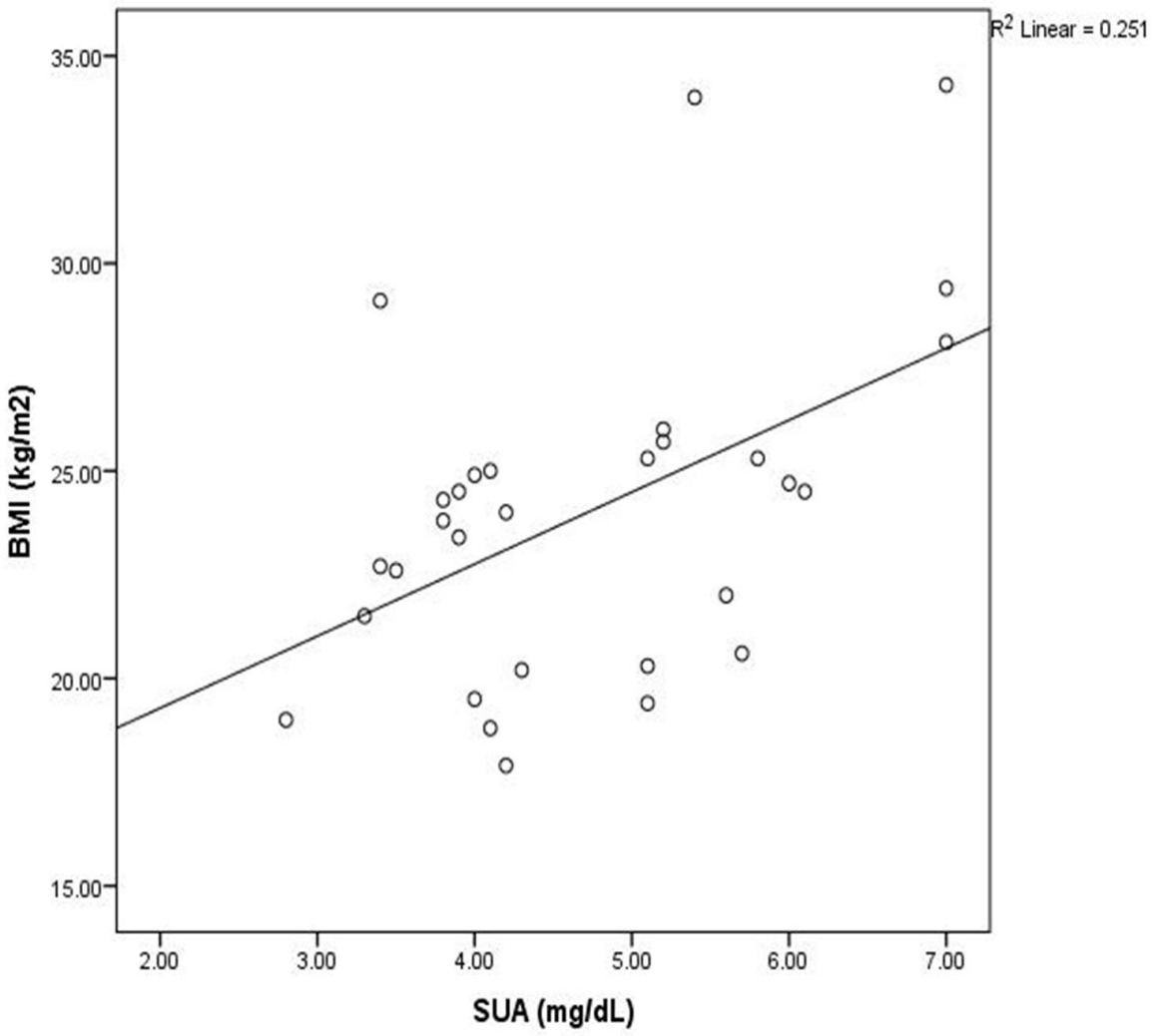


Figure 3: Relationship between body mass index and serum uric acid among controls.

Correlation analysis among cases indicated that waist circumference has shown a significant positive correlation with BMI and IDRS among cases ($r= 0.442$, $p< 0.05$, $r= 0.784$, $p< 0.01$, respectively), shown in **Table 8, Figure 4, and Figure 5.**

Table 8: Correlations analysis among cases

	Age (years)	RBS (mg/dL)	SCr (mg/dL)	SUA (mg/dL)	UAE (mg/dL)	WC (cm)	BMI (kg/m^2)	IDRS
Age (years)	1	-0.231	-0.111	-0.092	-0.007	-0.327	-0.197	0.050
RBS (mg/dL)		1	0.059	0.278	0.090	-0.006	0.199	-0.040
SCr (mg/dL)			1	-0.049	0.085	0.237	0.129	0.254
SUA(mg/dL)				1	-0.024	0.077	0.243	0.109
UAE(mg/dL)					1	-0.034	-0.064	-0.040
WC (cm)						1	**0.442***	**0.784****
BMI (kg/m^2)							1	.321
IDRS								1

**. Correlation is significant at the 0.05 level (2-tailed).*

***. Correlation is significant at the 0.01 level (2-tailed).*

BMI: Body mass index, IDRS: Indian diabetes risk score, SCr: Serum creatinine, SUA: Serum uric acid, UAE: Urinary albumin excretion, WC: Waist circumference

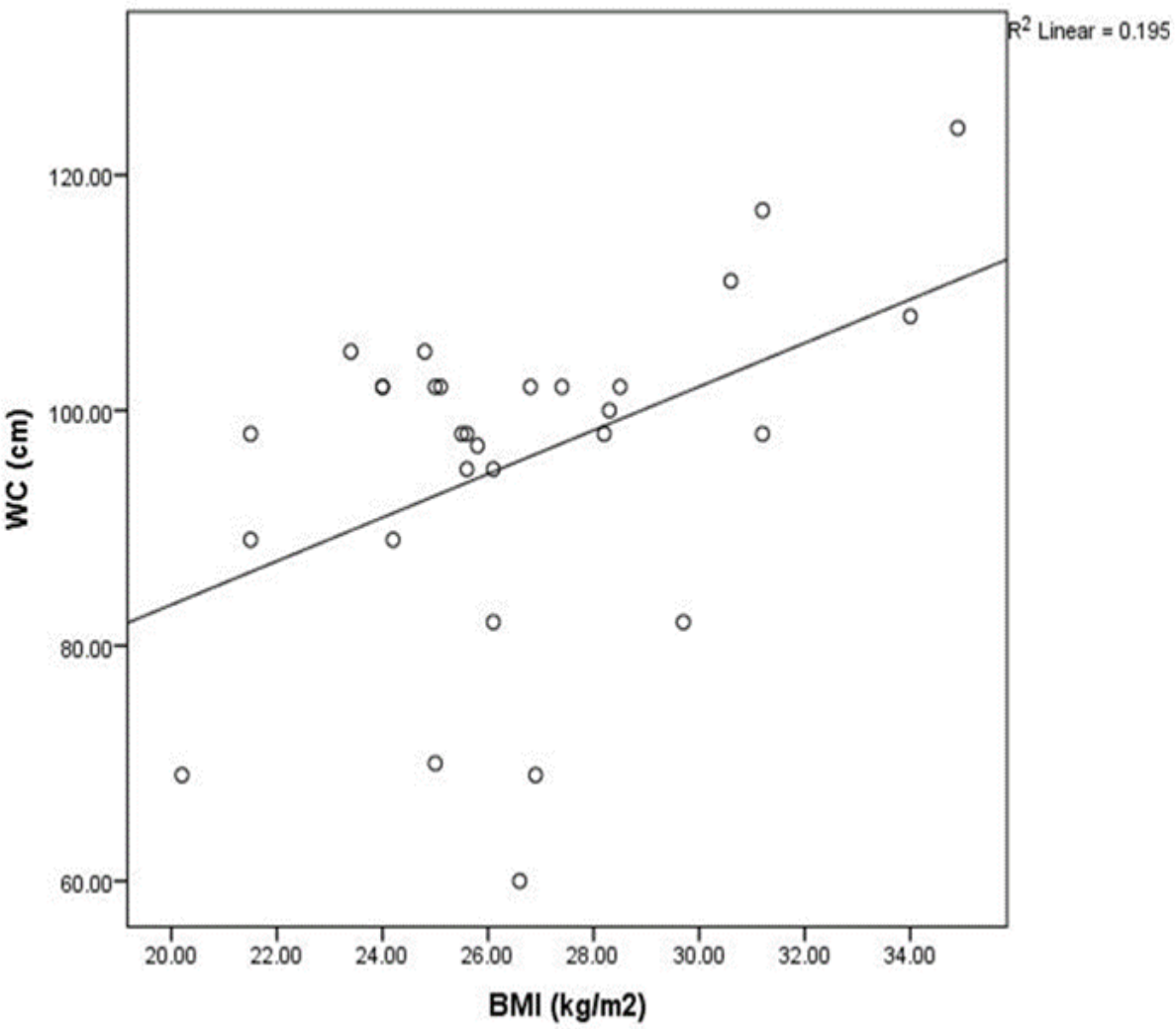


Figure 4: Relationship between waist circumference and body mass index among cases

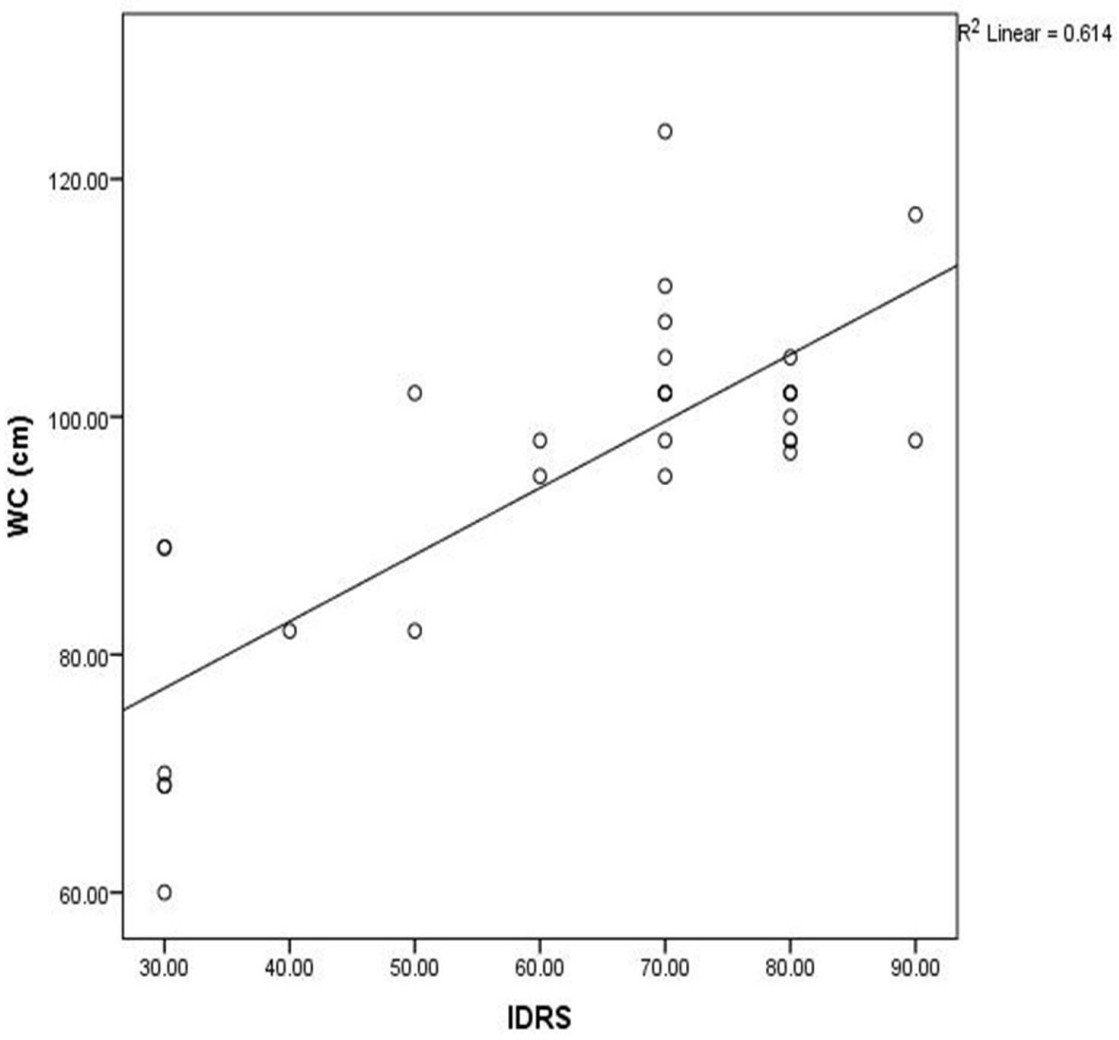


Figure 5: Relationship between waist circumference and IDRS among cases

DISCUSSION

DISCUSSION

The current investigation revealed that abdominal obesity affects 63% of patients and 30% of controls.The prevalence of abdominal obesity was determined to be 51.77% in adults and 57.91% in women, according to reports. (Gupta et al, 2023). In this addition, 73% of cases and 46% of controls were found physically inactive. A study reported that large numbers of people in India are physically inactive. It was further reported that less than 10% of people are physically active in India (Anjana et al, 2014). Additionally, it was shown that 16% of cases and 16% of controls have a history of diabetes in their families. According to a population study conducted in Kerala, 47.9% of those with a family history of diabetes are at high risk for developing the disease (Sathish et al., 2017). Nearly 75% of diabetics in India have a first-degree family history of diabetes and a strong familial aggregation. (Davey et al, 2000).

On the basis of IDRS, present study showed that 33% of controls and 36% of cases were at high risk (≥60). A West Tripura-based population study reported that about 34.2% of participants were at high risk of diabetes (Sengupta et al, 2021). However, a North Indian study reported that 67.2% of participants were at high risk of diabetes (Khan et al, 2017).

When compared to controls, the mean values for RBS, serum creatinine, serum uric acid, urine microalbumin, waist circumference, and BMI were all significantly higher in cases. It was noted that T2DM patients had considerably higher serum levels of uric acid and creatinine. Additionally, it was proposed that higher serum concentrations of uric acid and creatinine could be utilised as a useful diagnostic for detecting illness problems. (Al-Daghri et al 2017). According to reports, both men and women's WC has a substantial connection with and functions as an independent predictor of T2DM. However, considerable evidence linking BMI to T2DM in women (Bai et al 2022).

Serum uric acid has shown a significant positive association with WC, BMI and IDRS in controls. A population-based study reported that serum uric acid has shown a significant positive association with BMI in The China (Wang et al 2014). Similarly, the risk of hyperuricemia increases with increase of BMI in adolescents (Liu et al 2023). Serum uric acid has shown a significant positive association with general obesity in diagnosed T2DM patients. It was further suggested that serum uric acid should be routinely examined in new diagnosed T2DM patients to reduce the complications (Singh et al 2023). WC has shown a significant positive association with BMI and IDRS among cases. WC is a main modifiable risk factor of IDRS (Mohan et al 2005). WC is a marker of abdominal obesity and independent predictor of T2DM, cardiovascular diseases and overall mortality (Ross et al 2020, Powell-Wiley et al 2021).

It was reported that T2DM is the leading cause of CKD and its-associated deaths (Deng et al 2021). The global prevalence of CKD is about 9.1%. In addition, about 31% of CKD-associated disability was contributed by T2DM (Bikbov et al 2020).

A recent study reported that IDRS is a most suitable, easy and effective screening tool for diabetes in Asian Indian population (Deepa et al2023). In addition, a recent study reported that diabetes is mostly affecting kidney about 42.8% (Sathish et al 2023). IDRS is validated for screening of diabetes, abdominal obesity, metabolic syndrome, cardiovascular diseases (Khan et al 2017, Khan et al 2023, Gupta et al 2023). A recent systematic review reported that various diabetes risk score can be used for early screening of CKD in T2DM patients (González-Rocha et al 2023).

Limitations of the research

The current investigation has not provided any conclusive or substantial findings to validate IDRS and diabetic nephropathy due to the small sample size and time constraints. For IDRS and diabetic nephropathy to be validated, additional research with a large sample size is necessary.

SUMMARY AND CONCLUSION

SUMMARY

In this case control study, 60% of cases and 80% of controls was found ranging from 35 to 49 years of age. In addition, 40% of cases and 20% of controls was found the age-group more than 50 years. In addition, it was found that 63% of cases and 30% of controls have abdominal obesity. In this addition, 73% of cases and 46% of controls were found physically inactiveAdditionally, 16% of patients and 16% of controls were found to have relatives with a history of diabetes.

Based on their IDRS scores, the participants were grouped in at low risk (<30), at moderate risk (30–50), and high risk (≥60). Results shown that 10% controls were at low risk, 18% controls were at moderate risk, and 33% controls were at high risk. Similarly, it was found that 13% cases were at moderate risk, and 36% cases were at high risk.

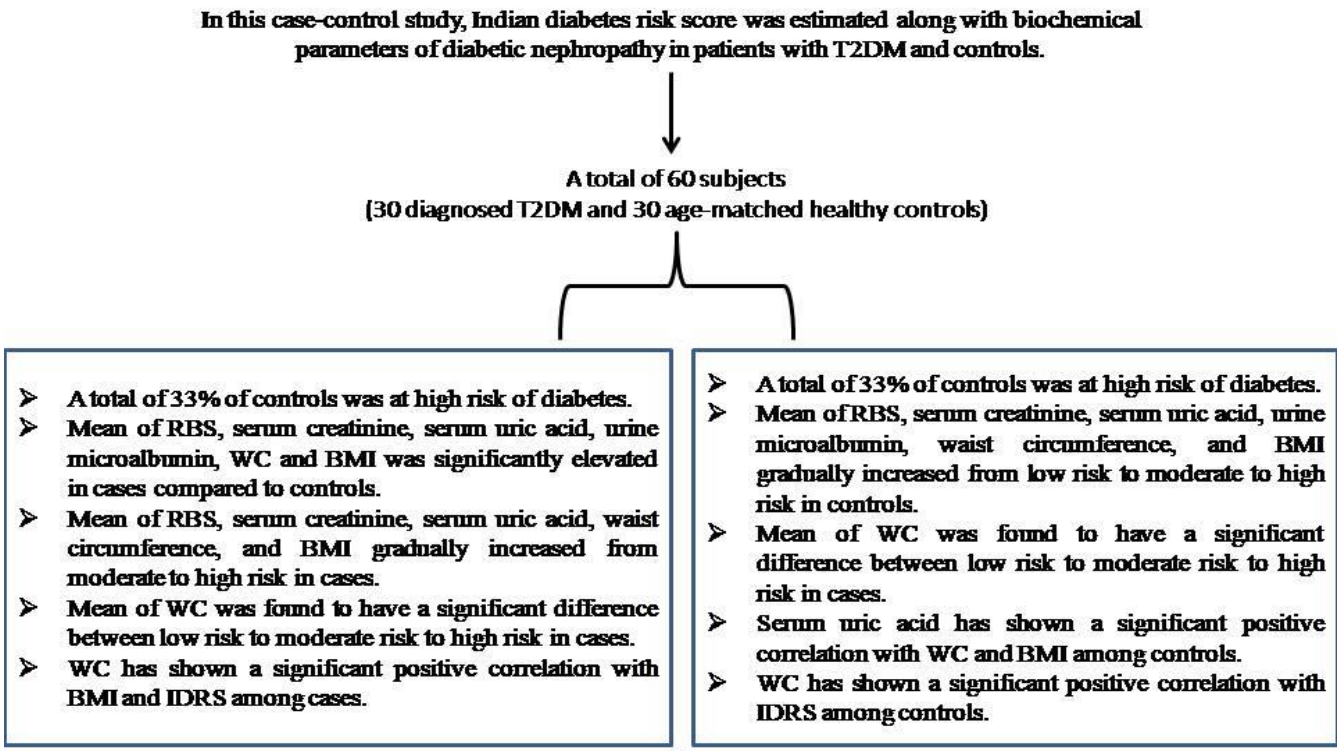
Mean of RBS, serum creatinine, serum uric acid, urine microalbumin, waist circumference and BMI was significantly elevated in cases compared to controls, BMI gradually rose from low risk to moderate risk to high risk. In controls, there was a significant difference in waist circumference between those at low, moderate, and high risk as indicated**.** Mean of WC was found significant difference between moderate risk and high risk in cases.

The results of a correlation analysis among controls revealed a substantial positive connection among serum uric acid and waist circumference and BMI Waist circumference has a strong positive link with BMI and IDRS among cases, according to a correlation analysis of cases.

CONCLUSION

Results showed that mean of RBS, serum creatinine, serum uric acid, urine microalbumin, waist circumference and BMI was significantly elevated in cases compared to controls. Serum uric acid has shown a significant positive association with WC, BMI and IDRS in controls. Similarly, WC has shown a significant positive correlation with BMI and IDRS among cases.

SUMMARY


In this case-control study, Indian diabetes risk score was estimated along with biochemical parameters of diabetic nephropathy in patients with T2DM and controls.
A total of 60 subjects
(30 diagnosed T2DM and 30 age-matched healthy controls)
A total of 33% of controls was at high risk of diabetes.
Mean of RBS, serum creatinine, serum uric acid, urine microalbumin, WC and BMI was significantly elevated in cases compared to controls.
Mean of RBS, serum creatinine, serum uric acid, waist circumference, and BMI gradually increased from moderate to high risk in cases.
Mean of WC was found to have a significant difference between low risk to moderate risk to high risk in cases.
WC has shown a significant positive correlation with BMI and IDRS among cases.
A total of 33% of controls was at high risk of diabetes.
Mean of RBS, serum creatinine, serum uric acid, urine microalbumin, waist circumference, and BMI gradually increased from low risk to moderate to high risk in controls.
Mean of WC was found to have a significant difference between low risk to moderate risk to high risk in cases.
Serum uric acid has shown a significant positive correlation with WC and BMI among controls.
WC has shown a significant positive correlation with IDRS among controls.

BIBLIOGRAPHY

REFERENCES

1. Almond K, Doria A, Kahn CR. Putting the genes for type II diabetes on the map. Nat Med 2001;7:277–279.

2. Lin CH, Chang YC, Chuang LM. Early detection of diabetic kidney disease: Present limitations and future perspectives. *World Journal of Diabetes* 2016;*7*(14):290–301.

3. Hussain, S., Jamali, M. CHabib, AHussain.M S. Diabetic kidney disease: An overview of prevalence, risk factors, and biomarkers. *Clinical Epidemiology and Global Health*,(2021) *9*, 2-6.

4. Tabish S. A. Is Diabetes Becoming the Biggest Epidemic of the Twenty-first Century: *International journal of health sciences*, *(2007)*(2), V–VIII.

5. Pradeepa, R., & Mohan, V. Epidemiology of type 2 diabetes in India Indian journal of ophthalmology,(2012) 69(11), 2932-2938.

6. Galaviz, K. I., Narayan, K. M. V., Lobelo. Lifestyle and the Prevention of Type 2 Diabetes:*American journal of lifestyle medicine*, (2015)*12*(1), 4–20.

7. Dudeja, P., Singh, G., Gadekar, T., &Mukherji, S. (IDRS) as screening tool for diabetes in an urban slum:*Medical journal, Armed Forces India*, (2017)*73*(2), 123–128.

8. Huang P. L. A comprehensive definition for metabolic syndrome. *Disease models & mechanisms*,(2009) *2*(5-6), 231–237.

9. Gupta, S. K., Singh, Z., Purty, A. JKar. *Indian journal of community medicine : official publication of Indian Association of Preventive & Social Medicine*,(2010) *35*(3), 396–399.

10. IDF: International Diabetes Federation Diabetes Atlas 2021 10th Edition. Facts and Figures. https://idf.org/about-diabetes/facts-figures/

11. Kumar A, Gangwar R, Ahmad Zargar A, Kumar R, Sharma A. Prevalence of diabetes

in India: A review of IDF Diabetes Atlas 10th edition. Curr Diabetes Rev. 2023 Apr 13. DOI: 10.2174/1573399819666230413094200.

12. Acharya AS, Debbarma S, Rasania SK. Risk assessment of diabetes using the indian diabetes risk score in an urban resettlement colony of east Delhi. Indian J Community Heal. 2020;32(2):354–8.

13. Anand, K., Jain, S., Chopra, H. Indian Diabetes Risk Score (IDRS): An effective tool to screen undiagnosed diabetes. *Indian Journal of Community Health*,(2007) *34*(1), 130-135..

14. S. Anusuya G, Ravi R, GopalakrishnanS.. Prevalence of undiagnosed and uncontrolled diabetes mellitus among adults in South Chennai. Int J Community Med Public Heal. 2018;5(12):5200

15. Joshi SR. Indian diabetes risk score. J Assoc Physicians India. 2005;53(SEPT.):755–7..

16. Thomas W, Shen Y, Molitch ME. Rise in albuminuria and blood pressure in patients who progressed to diabetic nephropathy in the Diabetes Control and Complications Trial. J Am SocNephrol 2001;12:333–340

17. Gupta MK, Raghav P, Tanvir T, . Recalibrating the non-communicable diseases risk prediction tools for the rural population of Western India. BMC Public Health. 2022;22(1):376.

18. Singh N. Indian diabetes risk score: use beyond population screening for diabetes. Med J Armed Forces India. 2018;74:93–4.

19. Mohan V, Mathur P, Deepa R. Urban rural differences in prevalence of self-reported diabetes in India–the WHO-ICMR Indian NCD risk factor surveillance. Diabetes Res ClinPract. 2008;80:159–68.

20. Anjana RM, Pradeepa R, Deepa M. Prevalence of diabetes and prediabetes results of the Indian Council of Medical Research-India Diabetes tudy. Diabetologia. 2011;54:3022–7.

21. Mohan V, Sandeep S, Deepa M. A diabetes risk score helps identify metabolic syndrome and cardiovascular risk in Indians-the Chennai Urban Rural Epidemiology study (CURES-38). 2007;9:337–43.

22. Khan MM, Sonkar GK, Singh S. Importance of the Madras Diabetes Research Foundation-Indian diabetes risk score (MDRF-IDRS) for mass screening of type 2 diabetes. Int J Diabetes DevCtries. 2019;39:419–25.

23. Iyer SR, Iyer RR, Upasani SV. Diabetes mellitus in Dombivli: an urban population study. J AssocPhys India. 2001;49:713–716.

24. Allen Jr, J. C. (2011). Sample size calculation for two independent groups: A useful rule of the thumb. Proceedings of Singapore Healthcare, 20(2), 138-140.

25. Iseki K, Ikemiya Y, Iseki C, Takishita S. Proteinuria and the risk of developing end-stage renal disease. Kidney Int. 2003; 63:1468–74.

26. Xu Y, Wang L, He J.. Prevalence and control of diabetes in Chinese adults. JAMA. 2013; 310:948–59.

27. Li P, Chen Y, Liu J, Hong J.Efficacy and safety of tangshen formula on patients with type 2 diabetic kidney. 2015; 10:e0126027.

28. Gheith, O., Farouk, N., Nampoory, N.. Diabetic kidney disease: world wide difference of prevalence and risk factors. Journal of nephropharmacology,(2015) 5(1), 49–56.

29. Weir M. R. Microalbuminuria in type 2 diabetics: *Journal of clinical hypertension (Greenwich, Conn.)*,(2004) *6*(3), 134–143.

30. Alicic, R. Z., Rooney, M. T. Diabetic Kidney Disease: *Clinical journal of the American Society of Nephrology : CJASN*,(2017) *12*(12), 2032–2045.

31. Saeedi, P., Petersohn, I., Salpea, P., Malanda, Williams, R., & IDF Diabetes Atlas Committee (2019).

32. Goyal, R., &Jialal, I. Diabetes Mellitus Type 2. In *StatPearls*. StatPearls Publishing.(2022)

33. Bowers, 1..D. Clin Chem. 26; 551. 2. Bartel, H. Clin. Chem.Acta(1980) 37,193.

34. Henry R.J., Common C. and Winkelman J.W. Clinical Chemistry principles and Techniques, Hader& Row, Hagerstown, MD, 1970

35. Gross JL, De Azevedo MJ, SilveiroSP.. Diabetic nephropathy: diagnosis, prevention, and treatment. Diabetes care. 2005 Jan 1;28(1):164-76.

36. Shaheer AK, Tharayil JK, Krishna PW. Journal of clinical and diagnostic research: JCDR. 2017 Sep;11(9):BC01.

37. .Gupta RD, Kothadia RJ, Parray AA. Association between abdominal obesity and diabetes in India: 2023 Oct 1;12:100155.

38. Anjana RM, Pradeepa R, Das AK, Deepa M J BehavNutrPhys Act. 2014 Feb 26;11(1):26.

39. SathishM,Sudhan N, Subramani K,. Biomass-derived activated porous carbon from rice straw for a high-energy symmetric supercapacitor in aqueous and non-aqueous electrolytes. Energy & Fuels. 2017 Jan 19;31(1):977-85.

40. Davey MW, Montagu MV, Inze D. Fletcher J. Plant L-ascorbic acid: chemistry, function, . 2000 May 15;80(7):825-60.

41. Sengupta PP, Wang TJ, McGuire DK. estimate long-term atherosclerotic cardiovascular disease risk in patients with type 2 diabetes. Diabetologia. 2021 Jul;64:1583-94.

42. Khan MM, Sonkar GK, Alam R, . Validity of Indian Diabetes Risk Score and screening of diabetes in and around areas of Lucknow. Journal of Family Medicine and Primary Care. 2017 Apr;6(2):366.

43. Al-Daghri NM, Al-Attas OS, Wani K. Serum uric acid to creatinine ratio and risk of metabolic syndrome in Saudi type 2 diabetic patients. Scientific reports. 2017 Sep 21;7(1):12104.

44. Bai K, Chen X, Song R. Association of body mass index and waist circumference with type 2 diabetes mellitus in older adults: a cross-sectional study. BMC geriatrics. 2022 Dec;22(1):1-0

45. Wang Qin L, Yang Z, GuH,Association between serum uric acid levels and cardiovascular disease in middle-aged and elderly Chinese individuals. BMC cardiovascular disorders. 2014 Dec;14(1):1-8..

46. Liu B, Zeng M, Zhou Y, Zhang M. Relationship between bone mineral density and hyperuricemia in obesity: A cross-sectional study. Frontiers in Endocrinology. 2023 Mar 28;14:1108475.

47. Singh SK, Singh R, Singh SK. Prevalence of Obesity in an Indian Cross-Sectional Study. International Journal of General Medicine. 2023 Dec 31:1217-26.

48. Mohan V, Deepa R, Deepa M. A simplified Indian Diabetes Risk Score for screening for undiagnosed diabetic subjects. The Journal of the Association of Physicians of India. 2005 Sep 1;53:759-63.

49. Powell-Wiley TM, Poirier P, Burke LE. Obesity and cardiovascular disease: a scientific statement from the American Heart Association. Circulation. 2021 May 25;143(21):e984-1010.

50. Duan S, Lu F, Song D, Zhang C. Current challenges and future perspectives of renal tubular dysfunction in diabetic kidney disease. Frontiers in Endocrinology. 2021 Jun 10;12:661185.

51. Deepa, M., Elangovan, N., Venkatesan, U, 2023. *Indian Journal of Medical Research*, *157*(4), pp.239-249.

52. González-Rocha A, Colli VA, Denova-Gutiérrez E. Peer Reviewed: Risk Prediction Score for Chronic Kidney Disease in Healthy Adults and Adults With Type 2 Diabetes: Systematic Review. Preventing Chronic Disease. 2023;20.

ANNEXURE

Unique Identification No:

INTEGRAL INSTITUTE OF MEDICAL SCIENCES AND RESEARCH LUCKNOW -226026

INCLUSION AND EXCLUSION CRITERIA -CASES

Inclusion Criteria

S. N.	Criteria	YES	NO
1.	Diagnosed cases of T2DM based on (WHO, 2003)		
2.	Subjects within the age of 35 to 65 years		
3.	T2DM (Disease duration diagnosed to 10 years only)		

Exclusion Criteria

S. N.	Criteria	YES	NO
1.	Diabetes mellitus More than 10 years disease duration		
2.	Subjects suffering from Gastrointestinal and respiratory blood losses		

Subject is eligible for the study, if all **INCLUSION** criteria are **YES** and all **EXCLUSION**

Criteria are No.

INVESTIGATOR

STATEMENT

I have verified the data entered in the case report form and have determined

that it is complete, accurate and compatible with the source documents

Investigator's name Investigator's signature Date

Unique Identification No

IDENTIFIERS- CASES

Registration No:

Contact No:

Name:

Father's Name /Husband's Name:

Address:

DEMOGRAPHICS- CASES

Age:

Sex: Male Female

Place of Residence: Urban Rural

Social / Economical Status: a) Upper b) Upper Middle c) Lower Middle

d) Upper Lower e) Lower

Education: a) Illiterate b) Primary c) Middle d) High School e) Intermediate

f) Graduation g) Post-graduation & above

ANTHROPOMETRIC PARAMETERS- CASES

Height (mts)

Weight (kgs)

Waist circumference (cm):

Body Mass Index (kg/ m^2):

Physical activity (Sedentary/Moderate/Active):

Unique Identification No:

INTEGRAL INSTITUTE OF MEDICAL SCIENCES AND RESEARCH LUCKNOW -226026

INCLUSION AND EXCLUSION CRITERIA -CONTROLS

Inclusion Criteria

S. N.	Criteria	YES	NO
1.	Apparently healthy individuals		
2.	Subjects within the age of 35 to 65 years		

Subject is eligible for the study, if all **INCLUSION** criteria are **YES** and all **EXCLUSION** Criteria are **No.**

INVESTIGATOR

STATEMENT

I have verified the data entered in the control report form and have determined that it is complete, accurate and compatible with the source documents

Investigator's name Investigator's signature Date

Unique Identification No:

IDENTIFIERS- CONTROL

Registration No:

Contact No:

Name:

Father's Name /Husband's Name:

Address:

DEMOGRAPHICS- CONTROL

Age:

Sex: Male Female

Place of Residence: Urban Rural

Social / Economical Status:

Education: a) Illiterate b) Primary c) Middle d) High School e) Intermediate

f) Graduation g) Post-graduation & above

ANTHROPOMETRIC PARAMETERS- CONTROL

Height (mts)

Weight (kgs)

Body Mass Index (kg/ m^2)

ANNEXURE I (A)

INFORMED CONSENT FORM

1. I am TanmayPawaskar Sunil MSC Medical Biochemistry 3rd year student, IIMSR Lucknow.
2. For this study, I will take your 2 ml blood sample for the estimation of serum creatinine& uric acid.
3. The blood is only subjected for estimation of serum creatinine& uric acid and not for any other purpose.
4. There will be no charges /fees/any consideration will be given or taken for the study.
5. Your identity will be confidential and information and the result of your blood test will not be revealed to any other except you if you desire.
6. This study has nothing to do with your treatment nor is it going to hamper the same if you refuse to participate.
7. The study has nothing to do with your current treatment but may improve the knowledge and understanding of the disease process and that knowledge may or may not be helpful in future.
8. After knowing all the above details, would you like to participate in our study? YES / NO

CONSENT FORM

I……..…age.....W/OD/OS/O.....
..
R/O.....……. here with state that I have been duly informed about the study Titled: "UTILITY OF INDIAN DIABETIC RISK SCORE (IDRS) FOR SCREENING OF DIABETIC NEPHROPATHY IN TYPE 2 DIABETES MELLITUS PATIENTS AND CONTROL SUBJECTS" its prospects and consequences.

I hereby give informed and written consent for the collection of my blood sample for the above said study only.

Signature/thumb impression of the patient:

Signature/thumb impression of the witness

Signature of research scholar:

नुबंध I (ए)

सूचितसहमतिफॉर्म

मैंतन्मयपावस्करसुनीलएमएससीमेडिकलबायोकैमिस्ट्रीतृतीयवर्षकाछात्र, आईआईएमएसऔरआरलखनऊहूं।

इसअध्ययनकेलिए, मैंसीरमक्रिएटिनिनऔरयूरिकएसिडकेआकलनकेलिएआपके 2 मिलीलीटररक्तकानमूनालूंगा।
रक्तकेवलसीरमक्रिएटिनिनऔरयूरिकएसिडकेआकलनकेअधीनहैऔरकिसीअन्यउद्देश्यकेलिएनहीं।
कोईशुल्क/शुल्कनहींहोगा/अध्ययनकेलिएकोईविचारकियाजाएगायालियाजाएगा।

आपकीपहचानगोपनीयऔरजानकारीपूर्णहोगीऔरयदिआपचाहेंतोआपकेरक्तपरीक्षणकापरिणामआपकेअलावाकिसीअन्य कोप्रकटनहींकियाजाएगा।
इसअध्ययनकाआपकेउपचारसेकोईलेना-देनानहींहैऔरनहीयदिआपभागलेनेसेइंकारकरतेहैंतोइससेइसमेंबाधानहींआएगी।
अध्ययनकाआपकेवर्तमानउपचारसेकोईलेना-देनानहींहै,
लेकिनयहरोगप्रक्रियाकेज्ञानऔरसमझमेंसुधारकरसकताहैऔरयहज्ञानभविष्यमेंसहायकहोभीसकताहैऔरनहींभी।
उपरोक्तसभीविवरणोंकोजाननेकेबाद, क्याआपहमारेअध्ययनमेंभागलेनाचाहेंगे?हांनहीं

सहमतिप्रपत्र

मैं……आयु……डब्ल्यू/ओडी/ओएस/ओ……
.....आर/ओ.....यहाँयहबतानेकेसाथकिमुझेअध्ययनकेबारेमें विधिवतसूचितकियागयाहै: "यूटिलिटीऑफइंडियनडायबिटिकरिस्कस्कोर (IDRS)
फॉरस्क्रीनिंगऑफडायबिटिकनेफ्रोपैथीइनटाइप 2 डायबिटीजमेलिटसपेशेंट: एकेसकंट्रोलस्टडी"
संभावनाएंऔरपरिणाम।
मैंकेवलउपरोक्तअध्ययनकेलिएअपनेरक्तकेनमूनेकेसंग्रहकेलिएसूचितऔरलिखितसहमतिदेताहूं।

रोगीकेहस्ताक्षर/अंगूठेकानिशान:

साक्षीकेहस्ताक्षर/अंगूठेकानिशान शोधार्थीकेहस्ताक्षरः

INSTITUTIONAL ETHICS COMMITTEE (IEC)

IIMS&R INTEGRAL UNIVERSITY, LUCKNOW

IEC/IIMS&R/2023/61

CERTIFICATE

This is to certify that research work entitled **"Utility of Indian Diabetic Risk Score(IDRS) for Screening of Diabetic Nephropathy in Type 2 Diabetes Mellitus Patients and Control Subjects"** submitted by **Tanmay Sunil Pawaskar** for ethical approval before the Institutional Ethics Committee IIMS&R. The above mentioned research work has been approved by Institutional Ethics Committee, IIMS&R with consensus in the meeting held on **30th December 2022.**

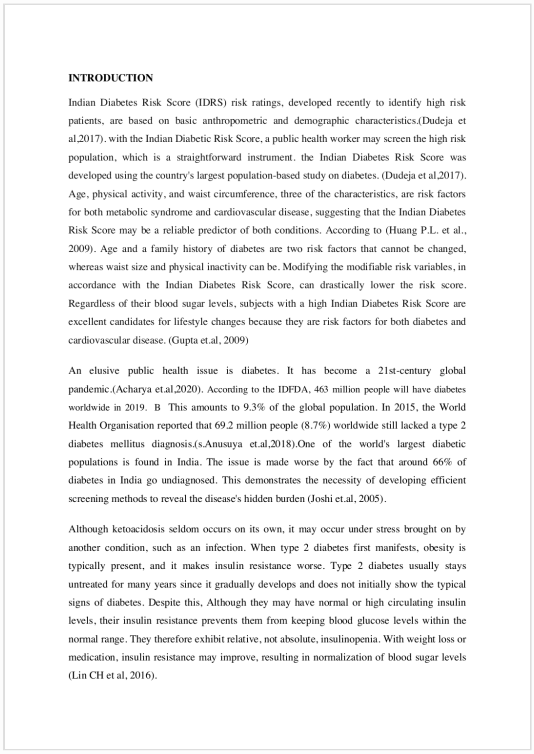
Dr.Q.S.Ahmed
(Member Secretary)
IRC/IEC
IIMS &R

Digital Receipt

This receipt acknowledges that Turnitin received your paper. Below you will find the receipt information regarding your submission.

The first page of your submissions is displayed below.

Submission author:	National Printers
Assignment title:	PC-1
Submission title:	Tanmay Pawaskar Plag report
File name:	for_plag_cheking.3.33.docx
File size:	185.51K
Page count:	16
Word count:	3,509
Character count:	18,592
Submission date:	17-Jul-2023 01:12AM (UTC-0500)
Submission ID:	1886341688



INTRODUCTION

Indian Diabetes Risk Score (IDRS) risk ratings, developed recently to identify high risk patients, are based on basic anthropometric and demographic characteristics.(Dudeja et al,2017). with the Indian Diabetic Risk Score, a public health worker may screen the high risk population, which is a straightforward instrument. the Indian Diabetes Risk Score was developed using the country's largest population-based study on diabetes. (Dudeja et al,2017). Age, physical activity, and waist circumference, three of the characteristics, are risk factors for both metabolic syndrome and cardiovascular disease, suggesting that the Indian Diabetes Risk Score may be a reliable predictor of both conditions. According to (Huang P.L. et al., 2009). Age and a family history of diabetes are two risk factors that cannot be changed, whereas waist size and physical inactivity can be. Modifying the modifiable risk variables, in accordance with the Indian Diabetes Risk Score, can drastically lower the risk score. Regardless of their blood sugar levels, subjects with a high Indian Diabetes Risk Score are excellent candidates for lifestyle changes because they are risk factors for both diabetes and cardiovascular disease. (Gupta et.al, 2009)

An elusive public health issue is diabetes. It has become a 21st-century global pandemic.(Acharya et.al,2020). According to the IDFDA, 463 million people will have diabetes worldwide in 2019. B This amounts to 9.3% of the global population. In 2015, the World Health Organisation reported that 69.2 million people (8.7%) worldwide still lacked a type 2 diabetes mellitus diagnosis.(s.Anusuya et.al,2018).One of the world's largest diabetic populations is found in India. The issue is made worse by the fact that around 66% of diabetes in India go undiagnosed. This demonstrates the necessity of developing efficient screening methods to reveal the disease's hidden burden (Joshi et.al, 2005).

Although ketoacidosis seldom occurs on its own, it may occur under stress brought on by another condition, such as an infection. When type 2 diabetes first manifests, obesity is typically present, and it makes insulin resistance worse. Type 2 diabetes usually stays untreated for many years since it gradually develops and does not initially show the typical signs of diabetes. Despite this, Although they may have normal or high circulating insulin levels, their insulin resistance prevents them from keeping blood glucose levels within the normal range. They therefore exhibit relative, not absolute, insulinopenia. With weight loss or medication, insulin resistance may improve, resulting in normalization of blood sugar levels (Lin CH et al, 2016).

Tanmay Pawaskar Plag report

by National Printers

Submission date: 17-Jul-2023 01:12AM (UTC-0500)
Submission ID: 1886341688
File name: for_plag_cheking.3.33.docx (185.51K)
Word count: 3509
Character count: 18592

INTRODUCTION

Indian Diabetes Risk Score (IDRS) risk ratings, developed recently to identify high risk patients, are based on basic anthropometric and demographic characteristics.(Dudeja et al,2017). with the Indian Diabetic Risk Score, a public health worker may screen the high risk population, which is a straightforward instrument. the Indian Diabetes Risk Score was developed using the country's largest population-based study on diabetes. (Dudeja et al,2017). Age, physical activity, and waist circumference, three of the characteristics, are risk factors for both metabolic syndrome and cardiovascular disease, suggesting that the Indian Diabetes Risk Score may be a reliable predictor of both conditions. According to (Huang P.L. et al., 2009). Age and a family history of diabetes are two risk factors that cannot be changed, whereas waist size and physical inactivity can be. Modifying the modifiable risk variables, in accordance with the Indian Diabetes Risk Score, can drastically lower the risk score. Regardless of their blood sugar levels, subjects with a high Indian Diabetes Risk Score are excellent candidates for lifestyle changes because they are risk factors for both diabetes and cardiovascular disease. (Gupta et.al, 2009)

An elusive public health issue is diabetes. It has become a 21st-century global pandemic.(Acharya et.al,2020). According to the IDFDA, 463 million people will have diabetes worldwide in 2019. B This amounts to 9.3% of the global population. In 2015, the World Health Organisation reported that 69.2 million people (8.7%) worldwide still lacked a type 2 diabetes mellitus diagnosis.(s.Anusuya et.al,2018).One of the world's largest diabetic populations is found in India. The issue is made worse by the fact that around 66% of diabetes in India go undiagnosed. This demonstrates the necessity of developing efficient screening methods to reveal the disease's hidden burden (Joshi et.al, 2005).

Although ketoacidosis seldom occurs on its own, it may occur under stress brought on by another condition, such as an infection. When type 2 diabetes first manifests, obesity is typically present, and it makes insulin resistance worse. Type 2 diabetes usually stays untreated for many years since it gradually develops and does not initially show the typical signs of diabetes. Despite this, Although they may have normal or high circulating insulin levels, their insulin resistance prevents them from keeping blood glucose levels within the normal range. They therefore exhibit relative, not absolute, insulinopenia. With weight loss or medication, insulin resistance may improve, resulting in normalization of blood sugar levels (Lin CH et al, 2016).

Weight gain, ankle and leg swelling, frequent nightly urination, morning sickness, anaemia, and high blood pressure are all indicators of kidney damage in diabetic patients. Albuminuria, or the excretion of albumin in the urine, is another sign and symptom. 30% of patients with type 1 diabetes and 40% of those with T2DM develop Diabetic kidney disease, respectively. End-stage renal disease and persistent kidney problems are primarily brought on by diabetic kidney disease. (Hussain et al., 2021).

Diabetes mellitus, once dismissed as a minor issue for the health of the world, is now recognised as one of the largest threats to public health in the twenty-first century. There has been a significant increase in the number of diabetes diagnoses worldwide during the past 20 years. Globally, the prevalence of diabetes mellitus is rapidly rising to epidemic levels. Around 366 million people had diabetes in the globe as of 2011, and 552 million will by 2030. Type 2 diabetes patients are becoming more prevalent in every country. According to estimates, 183 million people (about 50%) worldwide do not yet have diabetes. (Tabish. et al, 2007).

The rise of the economy was accompanied by an increase in diabetes prevalence. Diabetes is now widely prevalent in India, where it has reached 9% of the population overall and 20% in some of the wealthier southern towns. According to the IDF, India will have 100 million diabetics by 2030 (Pradeepa et al, 2021). Early detection of those who are at high risk would make it easier to implement suitable dietary changes and increased physical exercise, delaying or perhaps preventing the onset of diabetes. This means that identifying those who are at risk is crucial if we are to stop diabetes in India (Galaviz et al, 2015).

Diabetes has been dubbed the world's leading disease in India. Diabetes affects 19% of the population of the world in India (Gupta MK et al, 2022). By 2030, 80 million more people are predicted to suffer from T2DM (Singh N et al, 2018). IDRS it was shown that rural areas have a higher ratio of undiagnosed to diagnosed diabetic mellitus than non-rural, or urban, areas (Mohan V et al, 2008). This underlines the need for early action to prevent problems and community-wide awareness for screening. In India, the incidence of T2DM is higher in urban regions than in rural ones and it was discovered that the prevalence of pre-diabetes (14.5% in urban areas and 14.7% rural regions) was nearly comparable (Anjana RM et al, 2011).

Based on the Asian Indian phenotype, it was determined that Asian Indians were more likely

to have a bigger waist circumference, a lower body mass index (BMI), and more abdominal adiposity, making them more prone to T2DM and the diseases associated with diabetic nephropathy (CKD) (Mohan V et al, 2007). The frequency of CKD is increasing across the country, and it is more prevalent in urban than rural areas.(Khan MM et al, 2019).

REVIEW OF LITERATURE

End-stage renal failure (ESRD) is most commonly brought on by DKD an extremely harmful side effect of diabetes. An analysis predicted that China has an estimated 113.9 million diabetics (Iseki k et al, 2003). Extrapolations from cross-sectional research have revealed that up to 60% of Asian patients experience micro- or macroalbuminuria, and it's probable that 68 million Chinese people with diabetes also have DKD (Xu Y et al,2013) which would put a significant strain on the healthcare system. Early detection and treatment of DKD may lessen exposure to chronic renal disease and postpone or prevent ESRD. A risk score was developed without the requirement for a laboratory test as a step-by-step screening tool for undetected type 2 diabetes and has proven to be efficient and economical.(Li P et al,2015).

This crucial understanding made it possible for medical professionals to identify diabetic nephropathy considerably sooner than they had previously, allowing for earlier treatment approaches to stop the disease's progression. Microalbuminuria is the accumulation of 30 to 300 mg of albumin in the urine per 24 hours. Proteinuria or overt nephropathy is terms used to describe the condition when albumin levels are higher than 300 mg per 24 hours. Microalbuminuria has been referred to as "early diabetic nephropathy" or "incipient nephropathy," which to some signifies a young, maybe inconsequential disease that doesn't need treatment. But it must be emphasized that the earliest marker we are aware of is microalbuminuria. It is clear that the molecular alterations that have taken place over time in the kidney's glomeruli are what are causing albumin to now be produced in the urine. (Roshan et al, 2013).

The wealthy urban class's living habits are primarily to blame for this. Furthermore, their susceptibility is made worse by their ignorance of the importance of exercise, a balanced diet, and nutrition. Due to urbanisation and globalisation, there is a rise in the intake of high-fat, high-salt, and high-sugar (HFSS) meals. Many research studies among the urban population in India have been undertaken, but very few of them focused on the people who live in urban slums. (Lyer SR et al, 2001). Certain gene mutations, such as those in the glucokinase or hepatic nuclear factor genes that cause juvenile or early-onset diabetes, can be identified in

some families and are highly connected with specific types of diabetes (Almond et al, 2001).

End-stage renal disease (ESRD) is mostly brought on by diabetic nephropathy, and it is predicted that 20% of type 2 diabetic people will develop ESRD at some point in their lifespan. (Gheith el at, 2015). Clinically, the evolution of urine albumin excretion in diabetic kidney disease is typified by increasing rates of excretion from normoalbuminuria to microalbuminuria. and finally end-stage renal disease . The first clinically discernible stage of diabetic kidney disease is microalbuminuria, at which time effective therapies can slow or stop the disease's progression. (Weir M R et al, 2004).

Diabetic kidney failure (DKD) is a serious condition that impacts between 20 and 40 percent of people with diabetes. Diabetic renal disease is the main cause of end-stage kidney damage in the West. Both people with type 1 and type 2 diabetics can develop nephropathy, but type 2 diabetics are less likely to move on to end-stage renal disease. These patients account for over fifty per cent of all diabetics having hemodialysis because type 2 diabetes is more prevalent. (Alicic et al,(2017). Each year, there are more cases of DKD contributing to ESRD. Increased excretion of urine albumin or decreased glomerular filtration rate(GFR), or both, are signs of DKD, according to clinical care and epidemiological investigations. The frequency of diabetes has risen to epidemic levels worldwide. Over 550 million people are expected to have diabetes by the year 2035, up from the current projection of well than 8% of the world's population, or roughly more than 350 million people. More than 40% of persons with diabetes are predicted to develop chronic kidney disease (CKD) (Saeadi et al, 2019).

Patient with T2DM mellitus may frequently experience elevated blood sugar, cholesterol, and triglyceride levels for a prolonged length of time without showing any symptoms. Their diagnosis is really frequently postponed until the onset of complications or until the disease is accidentally discovered by a medical practitioner. Morbidity and early death stem from suboptimal management of diabetes and associated morbidities, insufficient health care facilities for early detection and beginning of therapy, and both. They experience several chronic problems that result in mortality and irreparable disability (Goyal et al, 2022).

Symptoms

You would probably not experience any signs or symptoms of diabetic nephropathy in its early stages.. In later stages, signs and symptoms may include:

- deteriorating blood pressure
- swelling of the hands, eyes
- greater frequency and rate of urine
- less insulin or diabetic medication is required
- concerns with confusion or attention
- breathing challenges

RESULTS

In this case control study, 60% of cases and 80% of controls was found ranging from 35 to 49 years of age. In addition, 40% of cases and 20% of controls was found the age-group more than 50 years. In addition, it was found that 63% of cases and 30% of controls have abdominal obesity. In this addition, 73% of cases and 46% of controls were found physically inactive. Further, it was found that 16% of cases and 16% of control have a family history of diabetes, shown in **Table 2.**

Table 2: Distribution of case and control as per IRDS

Particulars	**Score**	**Case N (%)**	**Control N (%)**
Age (YEARS)			
<35	0	0 (0%)	0(0%)
35-49	20	18(60%)	24(80%)
>50	30	12(40%)	6(20%)
Abdominal obesity			
Waist<80(female), <90 (male)-normal	0	4(13%)	10(33%)
Waist>80-89(female),>90-99cm(male)	10	7(23%)	11(36%)
Waist>90CM(female), 100cm(male)	20	19(63%)	9(30%)
Physical activity			
Exercise regular	0	5(16%)	10(33%)
Moderate work	20	3(10%)	6(20%)
Sedentary work	30	22(73%)	14(46%)
family history			
No family history	0	25(83%)	25(83%)
Either parent	10	4(13%)	0(0%)
Both parents	20	1(3%)	5(16%)

Based on their IDRS scores, the participants were divided into three groups: low risk, moderate risk, and high risk. Results shown that 10% controls were at low risk, 18% controls were at moderate risk, and 33% controls were at high risk. Similarly, it was found that 13% cases were at moderate risk, and 36% cases were at high risk, shown in Table 3.

Table 3: IDRS Distribution

IDRS	At Low Risk (<30) N (%)	At Moderate Risk (30-50) N (%)	At High Risk (≥60) N (%)
CONTROL	6(10%)	11(18%)	13(33%)
CASE	0(0%)	8(13%)	22(36%)
TOTAL	6(10%)	19(31%)	35(58%)

Mean of RBS, serum creatinine, serum uric acid, urine microalbumin, waist circumference and BMI was significantly elevated in cases compared to contros. shown in **Table 4.**

Table 4: Case and control baseline characteristics

Parameters	**Cases (Mean ± SD) (n= 30)**	**Controls (Mean ± SD) (n= 30)**	**P value**
Age (years)	47.40±9.61	42.97±8.49	0.06
RBS (mg/dL)	290.20±70.04	143.53±29.78	<0.001*
Serum Creatinine (mg/dL)	1.61±0.34	0.94±0.15	<0.001*
Serum Uric Acid (mg/dL)	5.47±1.21	4.73±1.15	0.02*
Urine Microalbumin (mg/dL)	120.18±32.25	15.15±4.39	<0.001*
Waist Circumference (cm)	95.70±14.10	86.37±9.90	0.004*
BMI (kg/m^2)	26.59±3.36	24.03±3.98	0.01*

Based on the IDRS, biochemical parameters were analyzed. Mean of RBS, serum creatinine, serum acid, urine microalbumin, waist circumference, and In controls, BMI gradually rose

from low risk to moderate risk to high risk. In controls, there was a significant difference in waist circumference between those at low, moderate, and high risk as indicated in Table 5.

Table 5: Biochemical parameters among controls as per IDRS

Parameters	6(10%) (IDRS <30)	11(18%) (IDRS =30-50)	13(33%) (IDRS ≥60)	P <0.05
Age (years)	36.67±2.87	46.91±11.29	42.54±4.78	0.045*
RBS (mg/dL)	139.17±30.20	136.82±25.89	151.23±30.85	0.45
Serum Creatinine (mg/dL)	1.00±0.13	0.93±0.15	0.93±0.16	0.60
Serum Uric Acid (mg/dL)	4.10±0.55	4.75±1.15	5.01±1.23	0.26
Urine Microalbumin (mg/dL)	14.10±3.210	15.46±3.92	15.38±5.14	0.81
Waist Circumference (cm)	72.17±6.64	85.55±7.97	93.62±2.47	<0.001**
BMI (kg/m^2)	23.65±3.57	23.57±2.74	24.58±4.88	0.79

Based on the Indian diabetic risk score, biochemical parameters were analyzed. Mean of RBS, serum creatinine, serum acid, waist circumference, and BMI gradual increased from moderate

to high risk in cases. Mean of waist circumference was found significant difference between moderate risk to high risk in cases (p <0.001), shown in **Table 6.**

Table 6: Biochemical parameters among cases as per IDRS

Parameters	**0(0%) (IDRS <30)**	**8(13%) (IDRS =30-50)**	**22(36%) (IDRS ≥60)**	**P <0.05**
Age (years)	-	48.38±11.22	47.05±8.93	0.74
RBS (mg/dL)	-	267.38±30.96	298.50±77.99	0.29
S. Creatinine (mg/dL)	-	1.46±0.33	1.67±0.33	0.13
S. Uric Acid (mg/dL)	-	4.98±0.99	5.65±1.23	0.18
Urine Microalbumin(mg/dL)	-	122.54±31.14	119.33±32.61	0.81
Waist Circumference (cm)	-	78.75±13.13	101.86±8.12	<0.001**
BMI (kg/m^2)	-	24.74±2.46	27.26±3.39	0.07

The results of a correlation analysis among controls revealed a substantial positive connection among serum uric acid and waist circumference and BMI (r = 0.366, p 0.05, and r = 0.501, p

0.01, respectively). Waist circumference and IDRS had a substantial positive connection (r = 0.845, p 0.01) shown in **Table 7**

Table 7: Correlations analysis among controls

	Age (years)	RBS (mg/dL)	SCr (mg/dL)	SUA (mg/dL)	UAE (mg/dL)	WC (cm)	BMI (kg/m^2)	IDRS
Age (years)	1	-0.083	-0.096	0.067	-0.248	-0.028	0.158	0.010
RBS (mg/dL)		1	-0.202	-0.098	-0.269	0.296	0.238	0.262
SCr (mg/dL)			1	0.054	-0.134	-0.233	0.268	-0.248
SUA(mg/dL)				1	0.229	**0.366***	**0.501****	0.227
UAE(mg/dL)					1	0.228	0.068	0.113
WC (cm)						1	0.089	**0.845****
BMI (kg/m^2)							1	-0.034
IDRS								1

.

Waist circumference has a strong positive link with BMI and IDRS among cases, according to a correlation analysis of cases (r= 0.442, p 0.05, and r= 0.784, p 0.01, respectively), as

demonstrated in Table 8

Table 8: Correlations analysis among cases

	Age (years)	RBS (mg/dL)	SCr (mg/dL)	SUA (mg/dL)	UAE (mg/dL)	WC (cm)	BMI (kg/m^2)	IDRS
Age (years)	1	-0.231	-0.111	-0.092	-0.007	-0.327	-0.197	0.050
RBS (mg/dL)		1	0.059	0.278	0.090	-0.006	0.199	-0.040
SCr (mg/dL)			1	-0.049	0.085	0.237	0.129	0.254
SUA(mg/dL)				1	-0.024	0.077	0.243	0.109
UAE(mg/dL)					1	-0.034	-0.064	-0.040
WC (cm)						1	**0.442***	**0.784****
BMI (kg/m^2)							1	.321
IDRS								1

DISCUSSION

The current investigation revealed that abdominal obesity affects 63% of patients and 30% of controls. The prevalence of abdominal obesity was determined to be 51.77% in adults and 57.91% in women, according to reports. (Gupta et al, 2023). In this addition, 73% of cases and 46% of controls were found physically inactive. A study reported that large numbers of people in India are physically inactive. It was further reported that less than 10% of people are physically active in India (Anjana et al, 2014). Additionally, it was shown that 16% of cases and 16% of controls have a history of diabetes in their families. According to a population study conducted in Kerala, 47.9% of those with a family history of diabetes are at high risk for developing the disease (Sathish et al., 2017). In India, there is a strong familial association and a first-degree family record of diabetes in about 75% of diabetics. (Davey et al, 2000).

On the basis of IDRS, present study showed that 33% of controls and 36% of cases were at high risk (≥60). A West Tripura-based population study reported that about 34.2% of participants were at high risk of diabetes (Sengupta et al, 2021). However, a North Indian study reported that 67.2% of participants were at high risk of diabetes (Khan et al, 2017).

When compared to controls, the mean values for RBS, serum creatinine, serum uric acid, urine microalbumin, waist circumference, and BMI were all significantly higher in cases. It was noted that T2DM patients had considerably higher serum levels of uric acid and creatinine. Additionally, it was proposed that higher serum concentrations of uric acid and creatinine could be utilised as a useful diagnostic for detecting illness problems. (Al-Daghri et al 2017). According to reports, both men and women's WC has a substantial connection with and functions as an independent predictor of T2DM. However, considerable evidence linking BMI to T2DM in women (Bai et al 2022).

In controls, serum uric acid significantly improved the relationship between WC, BMI, and IDRS. According to a population-based study, serum uric acid has a substantial positive correlation with BMI in China. (Wang et al 2014). Similar to this, teenagers' risk of developing hyperuricemia rises as their BMI rises (Liu et al., 2023). In patients with diagnosed T2DM, serum uric acid has demonstrated a substantial positive correlation with overall adiposity. Additionally, it was advised that in order to lessen the consequences, serum

uric acid testing should be done routinely on newly diagnosed T2DM patients. (Singh et al 2023). WC has shown a significant positive association with BMI and IDRS among cases. WC is a main modifiable risk factor of IDRS (Mohan et al 2005). WC is a marker of abdominal obesity and independent predictor of T2DM, cardiovascular diseases and overall mortality (Ross et al 2020, Powell-Wiley et al 2021).

According to reports, T2DM is the main factor causing chronic kidney disease (CKD) and the deaths that result from it. (Deng et al 2021). The global prevalence of CKD is about 9.1%. In addition, about 31% of CKD-associated disability was contributed by T2DM (Bikbov et al 2020).

A recent study reported that IDRS is a most suitable, easy and effective screening tool for diabetes in Asian Indian population (Deepa et al 2023). In addition, a recent study reported that diabetes is mostly affecting kidney about 42.8% (Sathish et al 2023). IDRS is validated for screening of diabetes, abdominal obesity, metabolic syndrome, cardiovascular diseases (Khan et al 2017). A recent systematic review reported that various Indian diabetes risk score can be used for early screening of CKD in T2DM patients (González-Rocha et al 2023).

Limitations of the research

The current investigation has not provided any conclusive or substantial findings to validate IDRS and diabetic nephropathy due to the small sample size and time constraints. For IDRS and diabetic nephropathy to be validated, additional research with a large sample size is necessary.

SUMMARY

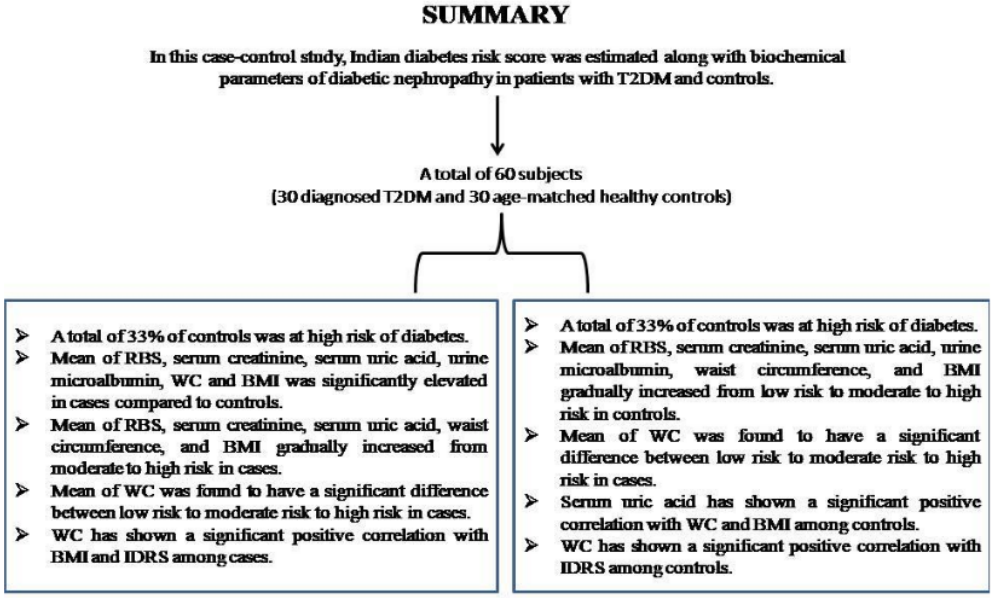
In this case control study, 60% of cases and 80% of controls was found ranging from 35 to 49 years of age. In addition, 40% of cases and 20% of controls was found the age-group more than 50 years. In addition, it was found that 63% of cases and 30% of controls have abdominal obesity. In this addition, 73% of cases and 46% of controls were found physically inactive. Additionally, 16% of patients and 16% of controls were found to have relatives with a history of diabetes.

Based on their IDRS scores, the participants were divided into three groups: low risk , moderate risk, and high risk. Results shown that 10% controls were at low risk, 18% controls were at moderate risk, and 33% controls were at high risk. Similarly, it was found that 13% cases were at moderate risk, and 36% cases were at high risk.

Mean of RBS, serum creatinine, serum uric acid, urine microalbumin, waist circumference and BMI was significantly elevated in cases compared to controls, BMI gradually rose from low risk to moderate risk to high risk. In controls, there was a significant difference in waist circumference between those at low, moderate, and high risk as indicated . Mean of waist circumference was found significant difference between moderate risk to high risk in cases. The results of a correlation analysis among controls revealed a substantial positive connection among serum uric acid and waist circumference and BMI Waist circumference has a strong positive link with BMI and IDRS among cases, according to a correlation analysis of cases.

CONCLUSION

Results showed that mean of RBS, serum creatinine, serum uric acid, urine microalbumin, waist circumference and BMI was significantly elevated in cases compared to controls. S. UA has shown a significant positive association with WC, BMI and IDRS in controls. Similarly, WC has shown a significant positive correlation with BMI and IDRS among cases.



Tanmay Pawaskar Plag report

ORIGINALITY REPORT

5%	3%	3%	1%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	www.researchsquare.com Internet Source	1%
2	Mohd Danish Khan, Mohammad Kaleem Ahmad, Roshan Alam, Geeta Jaiswal, Mohammad Mustufa Khan. "Utility of Indian diabetes risk score for the screening of type 2 diabetes mellitus and cardiovascular disease in and around areas of Lucknow", International Journal of Diabetes in Developing Countries, 2023 Publication	1%
3	pubmed.ncbi.nlm.nih.gov Internet Source	1%
4	mdpi-res.com Internet Source	1%
5	Amal Ahmed Abd El-Fattah, Nermin Abdel Hamid Sadik, Olfat Gamil Shaker, Amal Mohamed Kamal, Nancy Nabil Shahin. "Serum Long Non-Coding RNAs PVT1, HOTAIR, and NEAT1 as Potential Biomarkers in Egyptian	<1%

Women with Breast Cancer", Biomolecules, 2021
Publication

6	Endalamaw Tesfa, Abaineh Munshea, Endalkachew Nibret, Daniel Mekonnen, Mulusew Alemneh Sinishaw, Solomon Tebeje Gizaw. "Maternal serum uric acid, creatinine and blood urea levels in the prediction of pre-eclampsia among pregnant women attending ANC and delivery services at Bahir Dar city public hospitals, northwest Ethiopia: A case-control study", Heliyon, 2022 Publication	<1 %
7	www.degruyter.com Internet Source	<1 %
8	Nag, Tanmay, and Arnab Ghosh. "Indian diabetes risk score and clustering of metabolic syndrome phenotype in a rural community of Asian Indian origin", Diabetes Research and Clinical Practice, 2016. Publication	<1 %
9	hrcak.srce.hr Internet Source	<1 %

Exclude quotes	On	Exclude matches	Off
Exclude bibliography	On		