DISSERTATION SUBMITTED FOR THE MASTER'S DEGREE IN MEDICAL PHYSIOLOGY



Inspiring Excellence

TITLE

"ASSOCIATION BETWEEN KIDNEY FUNCTION TESTS AND DIFFERENT GRADES OF ANEMIA IN DIABETIC PATIENTS IN LUCKNOW REGION"

SUBMITTED BY

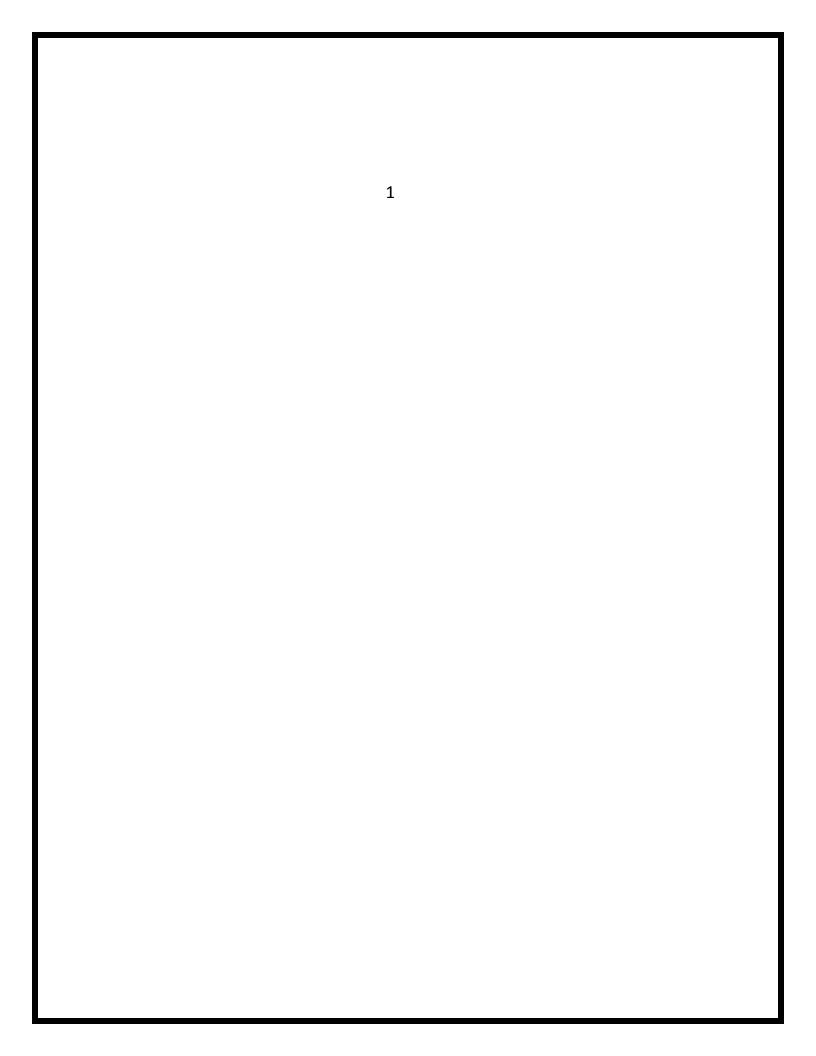
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TITLE

"ASSOCIATION BETWEEN KIDNEY FUNCTION TESTS AND DIFFERENT GRADES OF ANEMIA IN DIABETIC PATIENTS IN LUCKNOW REGION"

Dissertation submitted to

Integral Institute of Medical Sciences and Research

In partial fulfilment of the requirements for the award of degree of

Master of Science in Medical Physiology

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I hereby declare that this dissertation entitles "ASSOCIATION BETWEEN KIDNEY FUNCTION TESTS AND DIFFERENT GRADES OF ANEMIA IN DIABETIC PATIENTS" is a Bonafide & genuine research work carried out by me under the guidance of prof (Dr.) Khaleel Ahmed Manik, Professor & head, Department of Physiology and Co-supervision Dr. Sara Siddique , Assistant Professor, Department of physiology, and Dr. Ayasa Parveen, Assistant professor, Department of Medicine.

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This is to certify that the dissertation entitled "ASSOCIATION BETWEEN KIDNEY FUNCTION TESTS AND DIFFERENT GRADES OF ANAEMIA IN DIABETIC PATIENTS" is a bonafide & genuine research work carried out by MO. SHAQIB under the guidance of Dr.(proff) Khaleel Ahmed Manik, Professor & head, Department of Physiology and under the co- supervision of Dr. Sara Siddique , Assistant Professor, Department of Physiology, and Dr. Ayasa Parveen, Assistant Professor Department of Medicine, in partial fulfillment of requirement for the degree of Master of Science in Medical Physiology. The research methods and procedures described have been done by the candidate and result observed by the Guides periodically.

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Place

List of Abbreviations

CKD	Chronic kidney disease
DBP	Diastolic blood pressure
EPO	Erythropoietin
HB	Haemoglobin
MCV	Mean corpuscular volume
SBP	Systolic blood pressure

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INTRODUCTION

INTRODUCTION

Anemia is a clinical condition in which the oxygen carrying capacity of blood is reduced. It is characterized by reduction in the number of RBCs less than 4 million/ μ L or their content of hemoglobin less than 12 gm/dl or both.

Anaemia is define by both the World Health Organisation (WHO) criteria and by a threshold level of haemoglobin for initiation of investigation and management recommended by clinical practice guidelines. The WHO define anaemia as a haemoglobin level <13 g/dl for men and post menopausal women and <12 g/dl for pre-menopausal women [1-2].

Chronic Kidney Disease (CKD) is characterised by a progressive decline in renal function [3]. It is a condition in which the kidneys lose their normal function, particularly excretory and regulatory functions, as a result of infections, autoimmune diseases, diabetes, hypertension, cancer, or exposure to toxic chemicals [4]. CKD is on its way to becoming a major health issue [5] and is rapidly spreading throughout the world [6]. India has the highest prevalence of diabetics in the world, with a prevalence of 3.8% in rural adults and 11.8% in urban adults [5]. It is linked to poor outcomes in all stages of CKD [7].

Biochemical markers are important in accurate diagnosis, risk assessment, and therapy selection to improve clinical outcomes. Serum analysis of renal function markers such as urea, creatinine, uric acid, and electrolytes is used routinely instead of urine analysis, which is relatively uncomfortable for the patient **[8]**. Tests to measure blood urea nitrogen (BUN) **[9]** It is a significant nitrogenous end

product of the metabolism of proteins and amino acids [8] and creatinine [9] which is a creatine phosphate breakdown product in muscle [8] are eliminated by the kidneys. BUN is an indirect and imprecise measurement of renal function that measures the amount of urea nitrogen in blood and is directly related to renal excretory function. Creatinine tests are used to diagnose impaired renal function and to determine the amount of creatinine phosphate in the blood. Urea and creatinine are good indicators of a healthy kidney, and an increase in serum levels indicates kidney dysfunction [9]. BUN and serum creatinine are the most widely used and widely accepted parameters for assessing renal function [9-10]. Blood collection for serum analysis is an invasive technique that causes anxiety and discomfort to patients due to blood loss from frequent blood sampling and potentially increases the risk of blood borne diseases for both patients and health care professionals. As a result, a simple diagnostic test that provides a reliable assessment of disease status and stages and is beneficial to both clinicians and patients is required [3].

Chronic kidney disease (CKD) has emerged as a global public health issue, causing significant morbidity and mortality [11-12]. Anemia is a symptom of advanced CKD and is associated with a lower quality of life and an increased risk of death [13-15]. Renal anaemia develops as a result of CKD, and its prevalence rises as the disease progresses. Patients will inevitably develop end-stage renal disease as the disease progresses, necessitating dialysis or kidney transplantation [16]. Anemia is a common CKD complication [17]. Recombinant human erythropoietin (rhEPO) is currently used to treat anaemia associated with CKD. Super-physiological doses of erythropoiesis-stimulating agents were previously used to treat anaemia; however, this has been linked to an increased risk of cardiovascular events as well as endothelial dysfunction [18].

Anemia is a common finding in patients with chronic kidney disease (CKD), and it is known that its prevalence and severity increase as renal function declines. Furthermore, anaemia is linked to a variety of clinical symptoms and signs, resulting in a lower quality of life and an increased risk of morbidity and mortality in these patients [19-23].

Recent evidence suggests that vitamin D has pleiotropic effects in various organ systems based on the distribution of vitamin D receptors throughout the body [24]. In addition to its well-known effects on the metabolism of bones and minerals, vitamin D has been shown to be protective against a number of chronic illnesses, including anaemia linked to CKD [25]. In fact, prior research using information from the Third National Health and Nutrition Examination Survey and the Study to Evaluate Early Kidney Disease revealed that vitamin D insufficiency was significantly and independently related with anaemia in CKD patients who did not need dialysis [26-27].

A growing number of people around the world are suffering from chronic renal disease (CKD). The progressive nature of CKD and the resulting end stage renal disease (ESRD) are significantly taxing available resources in the world's healthcare system **[28]**. Multi-organ involvement and metabolic waste product buildup are both symptoms of chronic kidney disease. Elevated blood urea and creatinine, as well as hematologic, electrolyte, endocrine, and skeletal disorders, are the typical symptoms of these alterations **[29]**.

In glucose metabolism of carbohydrates, underutilization results in hyperglycemia. Diabetes is referred as one of the greatest health risks to people in the 21st century is century [30]. Diabetic nephropathy is one of the causes of chronic kidney failure, and DM is the main cause of renal morbidity and mortality [31].

The glomeruli are the site of the most frequent lesions, which are clinically linked to three glomerular syndromes: non-nephritic proteinuria, nephrotic syndrome, and chronic renal failure **[32]**.

End-stage renal disease is most frequently caused by diabetes [33] and the most typical reason for renal anaemia. Additionally, hyperglycemia may make anaemia more prevalent [34] and manifest more quickly than in those who have renal impairment due to other factors [35]. Damage to the renal interstitium, widespread inflammation, and the anaemia in diabetic nephropathy has all been linked to autonomic neuropathy (DN) [36].

Diabetes mellitus (DM) and chronic kidney disease (CKD) are powerful independent risk factors for CV events and progression to end-stage renal disease (ESRD) [**37-38**]. Patients with both conditions are thus at an extremely high risk of adverse events, and diabetic nephropathy is the most common cause of ESRD in North America, accounting for roughly 40% of patients requiring incident dialysis [**39-40**].

Anemia is common in diabetic patients and is associated with the major diabetic complications including nephropathy, retinopathy, and CVD [41]. Some studies have shown that low haemoglobin (Hgb) concentrations, with or without albuminuria, are a risk factor for the progression of CKD [42-44]. Although several factors contribute to diabetes's high prevalence of anaemia, erythropoietin (EPO) deficiency appears to be one of the major causes [45]. While it has been reported that high EPO levels are associated with poor survival in patients with heart failure, diabetic chronic kidney disease (CKD), and kidney transplant recipients [46-48].

REVIEW OF LITRATURE

REVIEW OF LITRATURE

Glomerular filtration rates range from 20 to 40 ml/min, or higher than 177 mmol/l of serum creatinine, before anaemia of chronic renal failure is noticed. Shortened red cell survival, reduced EPO production, blood loss due to altered platelet function, and impaired erythropoiesis as a result of inhibitors or toxic metabolites are a few of the possible contributing factors to this anaemia[**49**].

Glucose homeostasis is severely altered in CKD patients, who are at high risk of both hyperglycemia and hypoglycemia. In this patient population, both high and low glycemic levels are associated with increased morbidity and shorter survival. Reduced renal gluconeogenesis, deranged metabolic pathways (including altered medication metabolism), and decreased insulin clearance are all associated with an increased risk of hypoglycemia in CKD patients. Reduced glucose filtration and excretion, as well as inflammation-induced insulin resistance, are risk factors for hyperglycemic episodes. In diabetic individuals with CKD at various stages, blood glucose control is not adequately standardised. Insulin has long been regarded as the safest anti-diabetic drug because of the higher risk of hypoglycemia in these patients. New anti-diabetic medications without insulin, however, have proven to be secure and efficient. To direct the glycemic control of patients with CKD, new modifications andguidelines are being released[**50**].

A study conducted by **Vitalis f et al**. In this study, they discovered that anaemia affected 2 out of 5 patients with type 2 diabetes. Since the existence of retinopathy and worsening kidney function were the independent causes of anaemia, diabetes complications were mostly to blame for this high incidence. A third of diabetic patients with normal renal function also had anaemia, which we also noticed**[51]**.

Anemia is linked to a variety of negative outcomes in patients with kidney dysfunction, including decreased exercise tolerance and quality of life, LVH, and congestive heart failure. Approximately twothirds of patients starting renal replacement therapy have LVH, and half have a history of cardiac failure. These findings suggest that the negative effects of anaemia can be seen before kidney failure develops. The current study's findings confirm the presence of anaemia in people with moderate kidney dysfunction and provide population-based estimates of the relationship between kidney function and haemoglobin levels[52].

Despite the fact that anaemia is a well-known risk factor for diminished athletic ability, many research have concentrated on severe cases of anaemia. They discovered that in these subjects with coronary disease, even modest decreases in haemoglobin (12 g/dl) were linked to decreased measured exercise capacity and decreased self-reported physical function. Furthermore, renal insufficiency was not a factor in

the connection between anaemia and poor physical function that was identified. These results are significant given that anaemia in individuals with coronary disease is often only treated if the haemoglobin level is 10 g/dl or the hematocrit is 30%[53].

Compared to CKD patients with normal testosterone levels, CKD patients with testosterone insufficiency were five times more likely to be anaemic. Their findings support prior research that found a correlation between testosterone levels and haemoglobin in various patient populations. According to the study, males with type-2 diabetes mellitus had a higher incidence of anaemia because of low testosterone levels[54].

A study conducted by **Chao Yang, et al**. Anemia in CKD is primarily caused by an inability of the kidneys to produce enough erythropoietin, but it is also influenced by reduced red blood cell survival and suppression of the marrow's response to anaemia. Contrarily, anaemia may also contribute to worsening kidney function, primarily through hypoxia and/or increased oxidative stress, as is suggested by the limited clinical study data. Anemia impairs the delivery of oxygen to tissues, which affects the function of various organs, including the heart. In China, anaemia is a risk factor for the deterioration of kidney function in the general population of middle-aged and old people. China has an ageing population, which poses a significant burden that demands more attention. Careful management and anemia-specific interventions may lower the incidence of renal failure and enhance general population prognosis[55].

A study conducted by Leila R, et al. Compared to adults without diabetes, adults with diabetes had a significantly greater prevalence of CKD and each of its component diseases from 2009 to 2014. Longer

diabetes duration was associated with a steady increase in CKD prevalence and its component diseases. After accounting for demographic factors and a number of BP-related variables, the elevated risks of CKD, albuminuria, and lower eGFR associated with diabetes were substantially attenuated, but the relationship between diabetes and the incidence of each CKD manifestation remained strong. In their analysis, a significant proportion of those with both diabetes and CKD also had CKD that was not caused by the presence of the disease; when demographics and blood pressure were taken into consideration, this proportion rose to 53%. Furthermore, it is likely that there are a variety of underlying reasons for the different CKD symptoms examined in this study. Regardless of the precise cause of CKD, the majority of current treatment recommendations for patients with diabetes and CKD, appropriate glycemic control, lipid-lowering therapy, and blood pressure control are appropriate[**56**].

A study conducted by **Thomas S, et al.** In their study, they looked at the prevalence of anaemia in connection to the presence of diabetes over a wide spectrum of kidney function, from near-normal to end-stage renal disease. Their finding may have substantial implications for anaemia screening in diabetic people because similar recent large-scale population studies found statistically significant differences in haemoglobin levels only in mild renal impairment. The present study has significant limitations, including the fact that no subject's erythropoietin levels were assessed in order to distinguish between erythropoietin deficit and resistance. Additionally, because formal quantification of autonomic function in diabetic subjects was not available and the data were presented in a format that limited its ability to be dissected out

in detail, it was impossible to determine whether autonomic neuropathy had any influence on the cause of anaemia in diabetic subjects[57].

A study conducted by **Kerri L, et al**. Diabetes and CKD are widespread conditions that impact a considerable majority of people. Drug regimes, such as those for glycemic management, and food intake may need to be modified depending on how severe the CKD is. Given the extremely high risk of adverse cardiovascular events in patients with both diabetes and CKD, aggressive identification and treatment of risk factors for cardiovascular disease as well as complications of CKD are advised. A haemoglobin value of less than 13 g/dl for men and less than 12 g/dl for women is considered anaemia in CKD, and annual examination is advised. Although studies in individuals with CKD (pre-dialysis) are scarce, anaemia correction to levels of 11–12 g/dl in dialysis patients has been linked to higher quality of life, fewer hospitalizations, and a lower risk of mortality[**58**].

AIM AND OBJECTIVES

AIM

To determine association of kidney function tests with anemia in diabetic patients in Lucknow.

OBJECTIVES

- To estimate Haemoglobin level of subjects.
- To estimate serum urea and creatinine level.
- To determine the association of kidney function test with anemia.

MATERIALS AND METHOD

TYPE OF STUDY – Cross-sectional Study.

PLACE OF STUDY - The study was performed in the Department of Physiology at Integral Institute Medical Science & Research, Lucknow (U.P.).

Duration of Study- 6 months. (february2022 to July2022)

INCLUSION CRIETERIA-

- 1. Subjects with diagnosed Diabetes and kidney function with various grades of anemia as per WHO norms.
- 2. Subjects (male & female).
- 3. Subject who had signed the Informed consent form.

EXCLUSION CRIETERIA-

- 1. Secondary causes of anemia including any organ transplant, malignancy, hemorrhage, hematological disorder, pregnancy.
- 2. Subjects with diseases, serum phosphorus levels at the highest 0.5% or lowest 0.5% to eliminate outliers and potential assay interactions.
- 3. History of Drug addicts and Alcoholic subjects.

Ethical Clearance- Has been taken from institutional ethics committee (IEC/IIMS&R/2022/26).

COLLECTION OF DATA

- Data of patients presenting to the (OPD & IPD) of Medicine Department of IIMS&R was collected.
- 2. Blood sample of patients was taken who have signed the informed consent.
- 3ml of blood was collected using all aseptic precaution in the clotting vials for estimation of blood urea, createnine by using Erba Chem-5 plus.
- 3 ml of blood was collected using all aseptic precaution in the EDTA vials for estimation of Haemoglobin by using Erba Mannheim.
- 1.5ml of blood was collected using all aseptic precaution in the fluoride vials for estimation of glucose by using Erba Chem-5 plus.

SAMPLE SIZE-

The sample size is calculated using the formula:

$$N = \frac{Z_{a/2}P(1-P)}{d^2}$$

N = Desired sample size

 $Z1-\alpha/2$ = Critical value and a standard value for the corresponding level of confidence. (At 95% CI or 5% level of significance (type-I error) it is 1.96)

p = Prevalence 44.1% (%Stauder R,;2014)

d = Margin of error or precision 5%

Non -response = 10% (Daniel WW;1999)

The study will include 145 cases diagnosed with kidney function tests and diffrents grades of anemia in diabetic patients.

RESULTS AND OBSERVATION

RESULTS AND OBSERVATION

Table no. 1 Grades of anemia: -

Table no. 1 shows that Out of 145 subjects, 59 (40.68) subjects have mild anemia, 60 (41.37) subjects have moderate anemia, and 26 (17.93) subjects have severe anemia.

	Number	Percentage
Mild	59	40.68%
Moderate	60	41.37%
Severe	26	17.93%
Total	145	100%

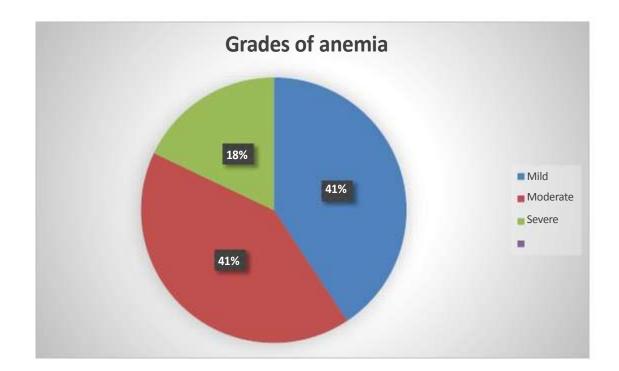


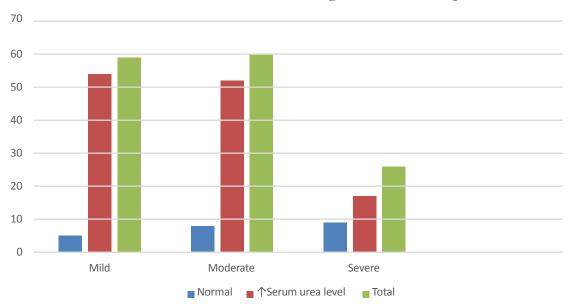
Table No. 2 - Association between Serum urea & different grades of Anemia subjects:-Table no. 2 shows that 54 subjects have increase serum urea level with mild anemia, 52 subjects have

increase serum urea level with moderate anemia, and 17 subjects have increase serum urea level with severe anemia.

5 subjects have mild anemia with normal serum urea level, 8 subjects have moderate anemia with normal

serum urea level, and 9 subject severe anemia with normal serum urea level.

	Normal	↑ Serum urea level	Total	$\chi^2 - \mathbf{P}$ value
Mild	5	54	59	9.8,
Moderate	8	52	60	0.00
Severe	9	17	26	



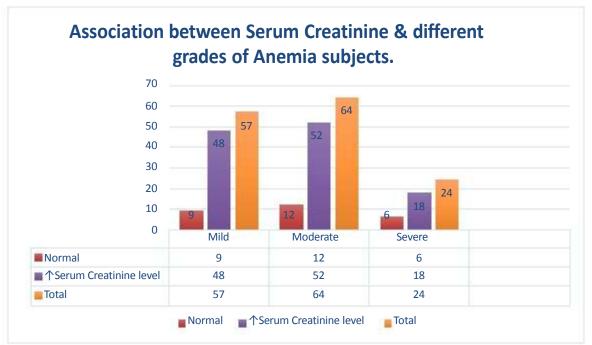
Association between Serum urea & different grades of Anemia subjects.

There were 145 patients. After analysing the above data, we identified that in our study using chi-square test, p-value is 0.00 and it shows association of serum urea with different grades of anemia was stastically significant.

Table No. 3 - Association between Serum Creatinine & different grades of Anemia subjects:-

Table no. 3 shows that 48 subjects have increase serum createnine level with mild anemia, 52 subjects have increase serum createnine level with moderate anemia, and 18 subjects have increase serum createnine level with severe anemia. 9 subject have mild anemia with normal serum createnine level, 12 subjects have moderate anemia with normal serum createnine level, and 6 subjects have severe anemia with normal serum createnine level.

	Normal	↑ Serum Creatinine level	Total	$\chi^2 - \mathbf{P}$ value
Mild	9	48	57	0.94,
Moderate	12	52	64	0.62
Severe	6	18	24	



There were 145 patients. After analysing the above data, we identified that in our study using chi-square test, p-value is 0.62 and it shows association of serum createnine with different grades of anemia was stastically not significant.

DISCUSSION

There were 145 patients. After analysing the data, we identified that in our study using chi-square test, p-value is 0.00 and it shows association of serum urea with different grades of anemia was statistically significant. In addition, similar results were obtain by **Ranjit LK**, et al. reported that The higher urea and creatinine levels in the anaemic group compared to the non-anaemic group support the risk of anaemia increasing significantly with deterioration of renal function. Within the anaemic group, patients with diabetic nephropathy (DN) had significantly lower Hb levels than those without DN. Anaemia is typically more severe and manifests earlier in patients with DN than in patients with CKD from other causes. **[59].**

Pandya D, et al. also reported that Based on the findings of the current study, serum urea and creatinine levels were significantly higher in CKD subjects, followed by diabetic and hypertensive subjects. Increased urea and creatinine levels were only seen in CKD, diabetic, and hypertensive subjects, with no difference seen in controls.[60].

Present study shows the association of serum createnine with different grades of anemia was statistically not significant. similar results were obtain by **Gouva C, et al**. Reported the interaction terms between baseline serum creatinine and treatment arm were not significant, implying that patients with high and low baseline creatinine received the same benefit. The relative hazards (RH) was 0.33 (P = 0.033) in the subgroup of patients with baseline serum creatinine >4 mg/dL (N = 22) and 0.43 (P = 0.077) in the subgroup of patients with baseline serum creatinine 4 mg/dL (N = 66) for doubling of creatinine, renal replacement, or death.[61].

Opposite finding were also reported by **Birhan W** et al. Moreover, **Birhan W**, **et al**. reported This study found that anaemia is a public health issue among diabetic patients in the study area. Furthermore, this study found a link between anaemia and renal function. Anaemia becomes more common as kidney function declines.[62].

CONCLUSION

CONCLUSION

The present study concluded that the decreased level of Hb is significantly associated with kidney function tests in diabetic patients in Lucknow region of India.

We can apply our results and its interpretation in prevention and detection of kidney function tests with different grades of anemia in diabetic patients.

Summary

Anemia is a clinical condition in which the oxygen carrying capacity of blood is reduced. It is characterized by reduction in the number of RBCs less than 4 million/ μ L or their content of hemoglobin less than 12 gm/dl or both.

Anaemia is define by both the World Health Organisation (WHO) criteria and by a threshold level of haemoglobin for initiation of investigation and management recommended by clinical practice guidelines. The WHO define anaemia as a haemoglobin level **[1-2]**.

Data of patients presenting to the (OPD & IPD) of Medicine Department of IIMS&R was collected. Blood sample of patients was taken who have signed the informed consent. 3ml of blood was collected using all aseptic precaution in the clotting vials for estimation of blood urea, createnine by using Erba Chem-5 plus. 3 ml of blood was collected using all aseptic precaution in the EDTA vials for estimation of Haemoglobin by using Erba Mannheim. 1.5ml of blood was collected using all aseptic precaution in the fluoride vials for estimation of glucose by using Erba Chem-5 plus.

There were 145 patients. After analysing the above data, we identified that in our study using chi-square test, p-value is 0.00 and it shows association of serum urea with different grades of anemia was stastically significant.

There were 145 patients. After analysing the above data, we identified that in our study using chi-square test, p-value is 0.62 and it shows association of serum createnine with different grades of anemia was stastically not significant .

Limitations

- □ This was a single centred, hospital based, cross-sectional study with small sample size (n=145). As a result, we cannot generalise our findings as there was no specific type of association found in our study.
- Demographical distribution also influences the Haemoglobin level and blood pressure.
- There were many confounding factors which could be excluded by considering large sample size from different regions so that specific association between KFT and different grades of anemia can be detected among population.

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ANNEXURE

CONSENT FORM

I.....Address.....

...... agree to participate in the research work

Topic "ASSOCIATION BETWEEN KIDNEY FUNCTION TESTS WITH DIFFERENT GRADES OF ANEMIA IN DIABITIC PATIENTS IN LUCKNOW REGION"

I have known the details of the research work very well and I give my consent for the same.

Date:

Signature/thumb impression of the patients:

Name of research scholar

Signature/thumb impression of the witness:

Signature of research scholar:

INFORMATION SHEET (FOR CASES)

I, MO.SHAQIB of Medical Physiology is a research scholar in IIMS&R.I

am associated with your treating doctor panel.

You are a newly diagnosed case of kidney function tests with anaemia and diabetes.

For this study, I will take few drops of your blood sample for the estimation of haemoglobin level.

The blood will be used for estimation of haemoglobin level and not for any other purpose.

I will also measure your blood pressure with Sphygmomanometer.

You will be neither charged for any of the above test nor be paid.

Your identity will be kept confidential and information and result of your blood test will not be revealed to any other except you if you, so desire.

The result of this test may or may not be helpful for your treatment but may improve the knowledge and understanding of disease and the knowledge may be helpful in future.

After having the all above information would you like to participate in our study? YES NO

INTEGRAL INSTITUTE OF MEDICAL SCIENCE & RESEARCH,

INTEGRAL UNIVESITY, LUCKNOW

II CASE REPORT PERFORMA

Registration No/Date:		OPD	IPD
Name (in capital):			
Father Name/Husband's Name:			
Mother Name:			
Date of Birth:			
Age:			
Sex: Male Marital status:		Female	
Permanent Address:			
Current Address:			
Mobile no:			
Category: GEN	OBC	SC	ST
Nationality			
Mather Tongue:			
\bigcirc			
Social/Economical Status:		Annual income (app	prox.)
Educational level:	Uneducated	/ Metric /Graduate / P	ostgraduate / Ph.D.
Vegetarian / Non-Vegetarian:			
Physical Activity:	Sedentary /	Moderate / Active	

सूचना फ्र

1. मै मो. शाकिब आईआईएमएसआर लखनऊ में शोध किद्यार्थी हूँ

2. इस परीक्षण 💽 ेे कलए ना ही शुल्क कलया अर्थि किया जायेगा .

3. इस िौरान आपि द्वारा िी गयी सारी जानिारी परीक्षण गोपनीय रखा जायेगा।

4. आप अगर चाहेंगे तो उसाि पररणाम आपिो बताया जायेगा।

आप इस अध्यन में अपनी स्वेच्छा से शाकमल अर्था इंिार िर सिते हैं।

6. इससे आपि इलाज पर िोई िुष्प्रभाि नहीं पडेगा।

7. इस समस्त तत्व िो समझते हुए क्या अध्यन में योगिान िेने िी सहमकत प्रिान िरते हैं हां / नहीं।

स्वीकृति / सहमति पत्र

मुझे अधय्यन शीर्षक ''किडनी फंक्शन टेस्ट और लखनऊ क्षे में मधुमेह रोकगयों में एनीकमया किल्ले किल्भन्न ग्रेड बीच सम्बन्ध ि

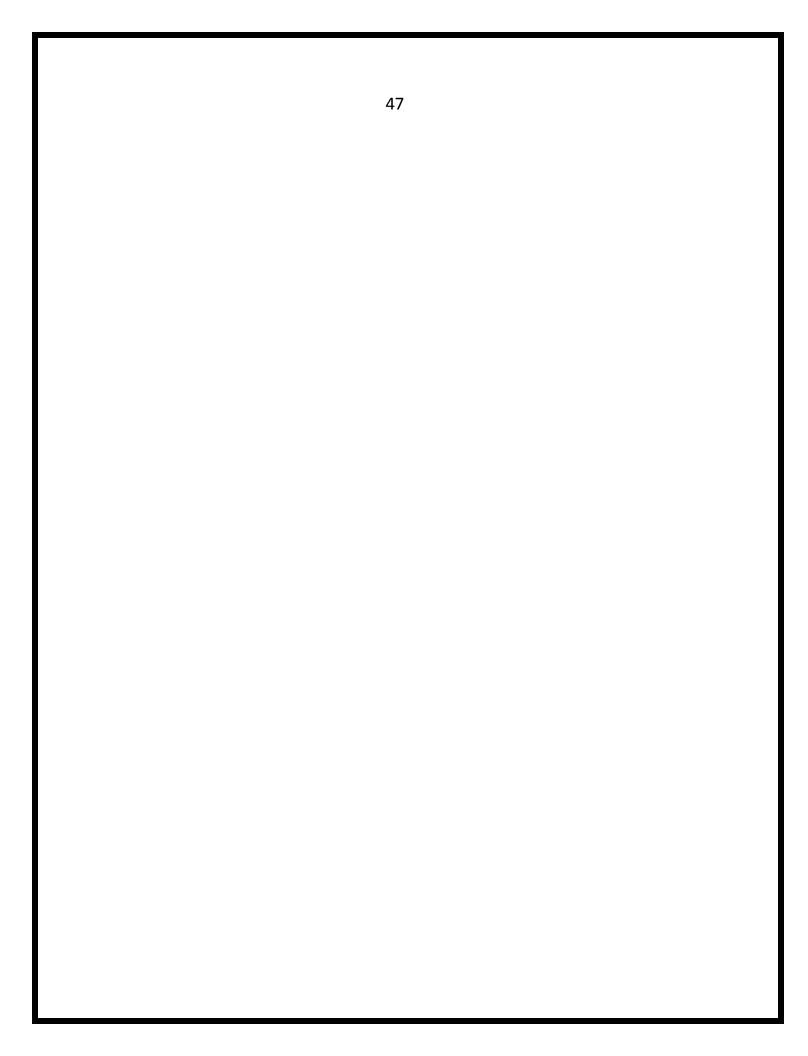
सम्भािनाओं एि पररणामो 💽 ेे बारे मे किकधित बताया गया है।।

अतः मै सूकचत िरता / िरती हूँ पि कलखखत सहमकत िेता / िेती हूँ , कि मेरे खत/पेशाब िा नमूना िेल्त ऊपर िहे गये अधय्यन िः ेः कलय एिकत्रत किया जाए ।

रोगी 💽 ेे हस्ताक्षर / अँगूठे 💽 ेे कनशान

शोध छात्र ििे हस्ताक्षर

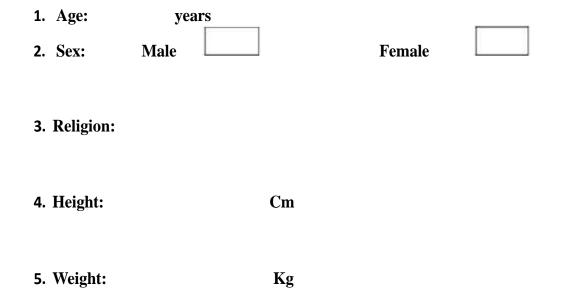
गिाह 💽 ेे हस्ताक्षर / अंगूठे 💽 ेे कनशान



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III <u>DEMOGRAPHICS</u>



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I-INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRIETRIA		
1. Subject with KFT with anemia and diabetes.		
2. Subject male & female.		
EXCLUSION CRITERIA		
1.secondary cause of anemia including any organ transplant.		
2.Subject with disease serum phosphorus levels at the highest		
0.5% or lowest 0.5% to eliminate outliers and potential assy in	traction.	
3. History Drug addicts and alcoholic subjects.		

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

<u>II.</u>	WORI	<u>KING PR</u>	OFORMA	
1. Registration No.:	Date	OPD	IPD	
2. Contact No:				
3. Name:		Age	Sex: a) Male	b) Female
4. Father 's Name:				
5. Place of Residence: a	a) Urban	b) Ru	ral	
6. Address:				
7. Marital status: a)	Unmarried b) Marrie	d c) Divorced	l d) Widow	
8. Education:				
9. Occupation:				
10. Diet: a) Vegetarian	b) Non-Vegetarian			
11. Height:				
12. Weight:				

<u>Family history</u>

1. Mother

<u>III.</u>

2. Father

a) Mother suffers from diabetic Disorders:

Yes, No Unknown

b) Father suffers from diabetic.

Yes, No Unknown

How many of them suffering from diabetic ?

IV.	MEDIC	CAL HIST	ORY
1. KFT :			
	Yes	Ν	0
2. MILD ANEMIC:			
3. MODERATE ANEMIC:			
4. SEVERE ANEMIC:			
	1	<u> </u>	_
5. Treatment:		L	
If yes, specify:			
- Duration of treatment:			
3. Patient complications; -	Low	Fair	High

INSTITUTIONAL ETHICS COMMITTEE (IEC) IIMS&R INTEGRAL UNIVERSITY, LUCKNOW



This is to certify that research work entitled <u>Association between kidney</u> function test and different grades Anemia in diabetic patients in Lucknow <u>Region</u> submitted by Mo. Shaqib, Dr. (Prof.) Khaleel Ahmad Manik, Dr. Ayesha Parveen, Dr. Sara Siddiquifor 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 19 May 2022.

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

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TO WHOM SO EVER CONCERNED

53

Plagiarism checked by:

Name of Faculty: Dr. Mohd. Musłufa Khan Designation: Assist. Brof. & Head Signature with date: MMAN Seal: 2010/202

> Dr. Mohd. Mustufa Khan Head Department of Basic Medical Sciences IIAHS&R, Integral University, Lucknow

Thesis work done by:

Name of Student: MO. SHAQIB Enrollment No. 1 200 10 26 80 Signature with date: Mol. Sabib 29/10/22



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