DISSERTATION SUBMITTED FOR THE MASTER'S DEGREE IN

MEDICAL PHYSIOLOGY

TITLE

"COMPARATIVE STUDY OF PULMONARY FUNCTION TESTS IN TYPE II DIABETIC AND NON-DIABETIC PATIENTS"

SUBMITTED BY

AYESHA FATIMA

ENROLLMENT NO: - 2000101328

DEPARTMENT OF PHYSIOLOGY

INTEGRAL INSTITUTE OF MEDICAL SCIENCES AND RESEARCH,

INTEGRAL UNIVERSITY, LUCKNOW – 226026 (U.P.) INDIA

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INTEGRAL INSTITUTE OF MEDICAL SCIENCES AND RESEARCH, INTEGRAL UNIVERSITY, LUCKNOW (U.P.) INDIA

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Masters of Science

In

Medical Physiology

By

AYESHA FATIMA

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GUIDE:	**CO-GUIDE:**	**CO-GUIDE:**
DR. SARA SIDDIQUI	DR. RAHUL SRIVASTAVA	DR. AUSAF AHMAD
ASSISTANT PROFESSOR	PROFESSOR & HOD	ASSOCIATE PROFESSOR
DEPT. OF PHYSIOLOGY	DEPT. OF RESPIRATORY MEDICINE	DEPT OF COMMUNITY MEDICINE

DEPARTMENT OF PHYSIOLOGY

INTEGRAL INSTITUTE OF MEDICAL SCIENCE AND RESEARCH, LUCKNOW-226026

INTEGRAL UNIVERSITY
Established Under U.P. Act no. 09 of 2004 by State Ligation
Approved by University Grants Commission
Phone No. : +91(0552)2890812,2890730,3296117,6451039
Kursi Road, Lucknow- 226026,Uttar Pradesh(India)

CERTIFICATE

This is to certify that this dissertation entitled: **"COMPARATIVE STUDY OF PULMONARY FUNCTION TESTS IN TYPE II DIABETIC AND NON-DIABETIC PATIENTS"** is a bonafide work carried out by **MISS AYESHA FATIMA,** post graduate student, **Department of Physiology,** ENROLLMENT NO:- **2000101328**, INTEGRAL INSTITUTE OF MEDICAL SCIENCE AND RESEARCH, LUCKNOW, under the guidance and supervision of **DR. SARA SIDDIQUI** in partial fulfilment of the regulations for the award of **Degree of Masters of Science In Medical Physiology** and is submitted to Integral Institute of Medical Science And Research, Lucknow.

The dissertation has been modified as per suggestion of the assessor. She has shown keen interest in preparing this dissertation and I have great pleasure in forwarding it.

I wish her good luck and bright future.

DR. KHALEEL AHMED MANIK
PROFESSOR & HOD
DEPARTMENT OF PHYSIOLOGY
VICE DEAN
IIMS&R, LUCKNOW

E-mail: info@integraluniversity.ac.in Web: www.integraluniversity.ac.in

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DR. SARA SIDDIQUI
GUIDE
ASSISTANT PROFESSOR
DEPARTMENT OF PHYSIOLOGY
IIMS&R, LUCKNOW

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CO-GUIDE
PROFESSOR & HOD
DEPARTMENT OF
RESPIRATORY MEDICINE
IIMS&R, LUCKNOW

DR. AUSAF AHAMAD
CO-GUIDE
ASSOCIATE PROFESSOR
DEPARTMENT OF
COMMUNITY MEDICINE
IIMS&R, LUCKNOW

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DECLARATION

I AYESHA FATIMA hereby declare that this Dissertation entitled **"COMPARATIVE STUDY OF PULMONARY FUNCTION TESTS IN TYPE II DIABETIC AND NON-DIABETIC PATIENTS"** is 'bonafide' in nature and was carried out by me for under the guidance and supervision of my guide **DR. SARA SIDDIQUI, ASSISTANT PROFESSOR, DEPARTMENT OF PHYSIOLOGY** Integral Institute of Medical Science And Research, Lucknow and has been modified as per suggestion of the assessor.

This dissertation is submitted to the Integral Institute of Medical Science And Research, Lucknow, in partial fulfilment of the university requirements for the award of Degree of Masters of Science in Medical Physiology.

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

Place: LUCKNOW

Date:

Candidate Name: AYESHA FATIMA

Department of Physiology

Enrollment No: - 2000101328

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AYESHA FATIMA

DATE-

PLACE- Lucknow

TABLE OF CONTENTS

ABBREVIATIONS

DM:	Diabetes Mellitus;
T2DM:	TYPE II Diabetes Mellitus;
IDDM:	Insulin dependent diabetes mellitus;
NIDDM:	Non insulin dependent diabetes mellitus;
BMI:	Body Mass Index;
WHO:	World Health Organisation;
PFTs:	Pulmonary Function Tests;
FVC:	Forced Vital Capacity;
FEV1:	Forced Expiratory Volume in 1st second;
FEV1/FVC%:	Forced Expiratory Volume in 1st second/Forced Vital Capacity ratio;
PEFR:	Peak Expiratory Flow Rate;
OPD:	Out Patient Department
IPD:	In Patient Department
FBS:	Fasting Blood Sugar;
BSPP:	Blood Sugar Post Prandial.
SD:	Standard Deviation;
β:	Beta cells;
α:	Alpha cells.

INTRODUCTION

INTRODUCTION

Diabetes mellitus is a group of metabolic disorders characterized by high blood glucose levels (hyperglycemia) due to problems with insulin secretion, insulin action, or both. [1]

It is classified into several types, with the two main types being Type I and Type II diabetes.

Type I Diabetes Mellitus also known as insulin-dependent diabetes mellitus (IDDM), is typically caused by an autoimmune response that leads to the destruction of insulin-producing beta cells in the pancreas. As a result, the body doesn't produce enough insulin, and individuals with Type I diabetes require lifelong insulin therapy to control their blood sugar levels. [2-3]

On the other hand, Type II Diabetes Mellitus previously referred to as non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes, is characterized by insulin resistance. In this condition, the body doesn't effectively use insulin, leading to elevated blood glucose levels. Type II diabetes is the most common form of diabetes, accounting for more than 95% of all diabetes cases. Historically, it was predominantly observed in adults, but it is now increasingly being diagnosed in children as well [4-5]

It's important to note that these are just general descriptions, and each individual's experience with diabetes may vary. Diabetes management involves various strategies, including medication, lifestyle modifications, and regular monitoring of blood sugar levels.

MODY (Maturity onset diabetes of the young), occurs when cells function of insulin activity are genetically deficient. It constitutes about 5% of all cases of diabetes. It is the Type 2 form of Diabetes Mellitus in youngish individualizes. Eleven types of MODY have lately seen. MODY 1 to MODY 11. Most common among them is MODY 3 that accounts for 20-75%. It happens as a result of a mutation in the HNF1- alpha gene (gene for hepatocyte nuclear factor 1 alpha). MODY 2 is the second most prevalent that accounts for 10-65%. It occurs due to mutation of glucokinase gene. Other forms of MODYs are less common. [2]

The prevalence of diabetes mellitus is a global issue, but it is more common in advanced European nations, the United States, and the Middle East. Asian Indians have one of the highest rates of diabetes in the world. [4-6]

According to the World Health Organisation, the total number of people living with diabetes is expected to reach 643 million by 2030 and 783 million by 2045. Three out of every four diabetics live in low- and middle-income nations. [7-8] Type 2 diabetes mellitus affects 2.4% of the rural population and 11.6% of the urban population in India.

Diabetes has 66.8 million patients in India in 2014, with a raw national prevalence (%) of 8.56.Diabetes is expected to be the seventh largest cause of death by 2030, according to the WHO. [9]

Changes in lifestyle, increasing calorie intake, sedentary lifestyle, junk food, environmental factors, and a stressful existence are some of the factors contributing to the rise in diabetes in India. [10]

Type 2 Diabetes Mellitus is associated with long-term damage, organ failure, and problems caused mostly by macro and micro-vascular damage and nerve damage. [1-11]

Diabetes micro-vascular complications, particularly retinopathy, nephropathy, and neuropathy, have long been recognised and handled in a variety of ways. However, diabetes-related microangiopathy may impair the alveolar capillary network in the lung, which is a big micro-vascular unit. This point to the lungs as a ***"Target organ"*** in Diabetes Mellitus. [11-12]

Diabetic retinopathy is a crucial cause of blindness and occurs as a result of long-term accumulated damage to the small blood vessels in the retina. Diabetes has rendered nearly one million individuals blind. [13]

The Pulmonary Function Tests (PFTs) are the primary tests used to assess an individual's physiological breathing performance. Pulmonary function tests (PFTs) are non-invasive physiologic tests used to determine how well the lungs work. The strength of respiratory muscles, compliance of the thoracic cavity, airway resistance, and elastic recoil of the lungs all influence pulmonary functioning. Because there is no single "normal" value or range for pulmonary function measurements, each one is unique. These metrics change depending on socio-demographic factors and anthropometric traits. [14]

The lung complications of type II diabetes mellitus mostly affect the mechanical aspects of the organ, with the restrictive pattern of lung complaint being the most common; these effects are reported by using Spirometry and measuring the forced vital capacity and forced expiratory volume in the first second, as well as the ratio between these two. [15]

Spirometry (means 'measuring the breath') is the most common of the pulmonary function tests (PFTs) which measures mechanical lung function, specifically the amount (volume) and/or speed (flow) of air that can be inhaled and exhaled.[11]

FVC: Forced vital capacity is the volume of air that can be quickly expelled with maximum force after a maximum inspiration.

FEV1 is the amount of air expelled in the first second of maximal expiration following a maximal inhalation. It is measured in L/sec. [16]

The ratio of FEV1 /FVC is a more sensitive indicator of airway obstruction than FVC or FEV alone. FEV1/FVC% gives a clinically useful index of air flow limitation.

Peak expiratory flow Rate (PEFR) refers to mechanical properties of the lung, like lung compliance and elastic recoil of lungs and reflecting larger airway function. It is the maximum speed of expiration, as measured with a peak flow meter. [14-16]

Pulmonary function tests decreased with rising FBS and PPBS, highlighting the pulmonary system as one of the Type-2 DM target organs. [17]

Criteria for diagnosis of DM:

American Diabetes Association Standards (ADA) Guidelines [4-11-18]

a) Post Prandial Blood Sugar ≥ 200 mg/dl
b) Fasting blood sugar ≥126 mg/dl

The World Health Organization (WHO) says Body Mass Index (BMI) is constantly used to identify obesity trends in a population. [19]

The formula used for BMI is weight in kilograms divided by height in meters squared = **BMI= Kg/m^2**

BMI <18.5 kg/m^2 is considered underweight,

BMI <25 kg/m^2 is considered normal,

BMI ≥25 kg/m^2 is considered overweight, and

BMI ≥30 kg/m^2 is considered obese.

World health organisation (WHO) also recommend BMI as the most useful population position measure of overweight and obesity, and is used as the same for the both sexes and in all ages of grown-ups. [20]

FIGURE -1 : SPIROMETER- PulmOne OF OUR RESPIRATORY MEDICINE DEPARTMENT OF INTEGRAL INSTITUTE OF MEDICAL SCIENCE & RESEARCH, LUCKNOW (IIMS&R) (U.P.)

REVIEW OF LITERATURE

REVIEW OF LITERATURE

1. A. Aparna et al, performed a cross-sectional and retrospective study in the year 2013 on **"Pulmonary Function Tests in Type 2 Diabetics and Non-Diabetic People -A Comparative Study".**40 were case group and 40 were control group out of total 80 patients. It says that FVC, FEV1 and PEFR were significantly reduced in type 2 diabetics as compared to those in controls and FEV1/FVC % was significantly increased in type 2 diabetics as compared to that in controls. The increased FEV1/FVC % suggested that the impairment of pulmonary functions in type 2 diabetics was primarily restrictive in nature.

2. Kalappan M., et al. performed a case control study in the year 2016 on **"Study on comparison of pulmonary function tests among diabetic and non-diabetic patients in a tertiary care hospital"**. In this he also focused on PFTs changes in diabetic smokers and non smokers. Study was among 100 sample patients equally distributed into 50-50 diabetic and non diabetic groups. The study revealed significant reduction in pulmonary functions among diabetics and also revealed significant impact of diabetes on pulmonary function independent of smoking.

3. Dhungel A, et.al performed a cross sectional comparative study in 2016 on **"Pulmonary Function Test among Diabetic and Non-Diabetic"**. He has taken 182 subjects, 91 Type 2 Diabetes-study groups, 91 Healthy-controls selected. Parameters were- FEV1, FVC, FEV1/FVC ratio, and PEFR. It shows that mean age of the patients in diabetic and non- diabetic group was as (53.1±5.9 vs. 51.3±11.4). The mean values of FVC, FEV1, and PEFR were statistically different between the two groups. The mean FVC falls dramatically as the duration of DM increases; however, this is not true for FEV1, FEV1/FVC%, or PEFR. When compared to the non-diabetic group, the diabetic group had considerably lower pulmonary function tests such as FEV1, FVC, and PEFR.

4. Shweta, A. K. Santa et.al, performed a case - control study in 2019 on **"A Comparative Study of Pulmonary Function Tests Type 2 Diabetes Mellitus and Non-Diabetes"**. 80 male subjects, 40 Type 2 Diabetes-study group, 40 Healthy-controls selected with age group of 40-55yrs. Parameters were- Forced vital capacity (FVC), Forced Expiratory Volume in 1st sec (FEV1), FEV1/FVC ratio, Forced Expiratory Flow in middle half of FVC (FEF 25-75%) and Peak

Expiratory Flow Rate (PEFR).Study group showed statistically greater percentage reduction in FVC, FEV1, FEF 25-75% and PEFR compared to control group. Type 2 Diabetes Mellitus may be a contributing factor to lung function abnormalities due to changed connective tissue, thickening of the basal lamina of the alveolar membrane and capillary endothelium, loss of bronchomotor tone, and respiratory muscle weakness.

5. Gangisetty SRG, Devarmani SS, et.al, performed a cross sectional study in 2018 on **"Study of Pulmonary Function in Patient with Type 2 Diabetes Mellitus"**. In this study he has taken 73 subjects in the diabetic group, 42 were males and 31 were females. And in the control group, 44 were males and 29 were females out of the 73. Patients in both the case and control groups were age and gender matched. Male and female FEV1, FVC, and FEV1 / FVC were compared. FEV1 and FVC were shown to be statistically insignificant. However, the mean FEV1/FVC ratio was 114.3 in males and 121.9 in females, with a significant p value of 0.018. PFT patterns were graded as mild, moderate, severe limitation, normal, normal with early sign of airway obstruction (ESAO), or normal with no restriction. The majority of controls (50% of total) had normal PFTs, whereas the majority of cases (37% each) had mild and moderate restrictive patterns. There were no diabetics identified with ESAO.

6. In 2017, Selvaraj S, Durai G, et.al performed a cross-sectional study **titled "A comparative study on pulmonary function tests in type 2 diabetics and non-diabetics in a tertiary care centre- Kanyakumari."** He recruited 100 patients between the ages of 30 and 50, 50 of whom had type 2 diabetes and 50 of whom had not. In his study, both FEV1 and FVC were reduced in diabetics, with FVC being reduced more than FEV 1, resulting in an increase in FEV1/FVC% and a significant 'p' value. Patients with diabetes have 14% normal pulmonary function tests, 80% have restrictive lung disease, and 6% have obstructive lung disease.In non-diabetics, 78% have normal lung disease, 12% have restrictive lung disease, and 10% have obstructive lung disease.

7. Pawar D., Pawar S., et al. conducted a case - control study on **"A comparative Study of Pulmonary Function Test (PFT) among Diabetic Cases and Matched Healthy Controls"** in 2015. The study included 110 individuals aged 31-50 years, with 55 previously diagnosed Type 2 Diabetes Mellitus patients (cases) and 55 healthy controls. FVC, FEV1, and FEV1% were chosen for the study and expressed as a percentage of expected normal values for age,

gender, and height using the Morris/Polgar Reference. Mean FVC, FEV1 was significantly lower in cases as compared to controls. Mean FEV1% was not significantly lower in cases as compared to controls. It concludes that the ventilator pulmonary function test results is showing restrictive lung disease pattern seems to be more likely due to type 2 diabetes.

8. Rajani M. et.al performed a cross-sectional descriptive study in the year 2013 on "**Study of Pulmonary Function Tests in Type-2 Diabetes Mellitus".** He has taken 40 Type-2 diabetics patients of 35-55 years age group and 40 healthy controls of the same age group were taken as control group. Out of the total 40 patients, 19 were males and 21 were females. In the study there is a decrease in the FVC, FEV1, PEFR, FEF 25-75% in type 2 diabetic patients as compared to non-diabetic controls. But there is an increase in the FEV1/FVC ratio in case groups in comparison with the controls. Pulmonary functions were decreasing with the increasing FBS, Blood Sugar PP, which underlines the respiratory system as one of the target organs of Type-2 DM.

9. In the year 2023 Rajput S, et al. performed a Comparative Cross-Sectional Study on **"Assessment of Pulmonary Functions and Dysfunctions in Type II Diabetes Mellitus:"** 100 people were taken 50-50 participants with and without type II diabetes mellitus. Pulmonary function parameters, including forced expiratory volume in one second (FEV1), forced vital capacity (FVC), FEV1 as a percentage of FVC in percentage (FEV1%), peak expiratory flow rate in L/second (PEFR). Except for FEV1% and PEFR, all PFT parameter values were lower in patients with diabetes mellitus compared to non-diabetics, indicating a heterogeneous pattern of lung dysfunction. FVC had a substantial negative connection with diabetes duration. Patients with type II diabetes mellitus had severe pulmonary impairment, with early involvement of restrictive factors.

10. Tesema D. et,al. performed a Comparative Cross-Sectional Study in the year 2019 on **"Pulmonary Function Tests and Their Associated Factors Among Type 2 Diabetic Patients".** The total sample size for study was 298 patients, (149 type 2 diabetics and 149 Non-diabetic) with the aged group ≥30 Years. Parameter were Forced vital capacity (FVC), forced expiratory volume in one second (FEV1), ratio of FEV /FVC, peak expiratory flow rate (PEFR), and forced expiratory flow (FEF25−75) were recorded by using a digital Spirometer. The current investigation found that the means of the PFTs in type II diabetes were considerably lower than in non-diabetics.

RESEARCH QUESTION

RESEARCH QUESTION

Is there any significant change in Pulmonary Function Tests in Type II Diabetic patients?

HYPOTHESIS

HYPOTHESIS

NULL HYPOTHESIS (H0)

There is no significant change of PFT in type 2 diabetic and non diabetic patients.

ALTERNATIVE HYPOTHESIS (H1)

There is significant change of PFT in type 2 diabetic and non diabetic patients.

AIM & OBJECTIVES

AIM & OBJECTIVES

AIM

Comparative study of Pulmonary Function Tests in Type 2 Diabetic and Non-Diabetic patients

OBJECTIVES

1) To study the change in pulmonary functions of individuals with Type 2 Diabetes Mellitus by performing Computerized Spirometry.

2) Comparison of pulmonary functions of diabetic with non-diabetic control group.

MATERIAL

&

METHODS

MATERIAL & METHODS

STUDY DESIGN-

A Case - Control study.

PLACE OF STUDY-

The study was performed in the Department of Physiology at Integral Institute of Medical Science & Research, Lucknow (IIMS&R) (U.P.)

DURATION OF STUDY-

Data collection – 4 Months

SUBJECT SELECTION -

Participants with age group of 40 – 60 years were selected with similar number of age, sex and BMI matched. The sample size is 60, comprising 30 cases (diagnosed with type II Diabetes Mellitus of minimum 6 months duration) and 30 controls (non-diabetic patients). After obtaining written informed consent form from both cases and controls, detailed histories were collected and general examinations were undertaken. All patients were given a proforma seeking through personal and medical background information.

INCLUSION CRITERIA-

1. Type II Diabetes Mellitus
2. Diabetics age group 40- 60 years
3. Diabetes Mellitus of minimum 6 month duration
4. Non- Diabetics
5. Non- Diabetics age group 40- 60 years

EXCLUSION CRITERIA-

1. Age less than 40 years.
2. Patients refusal
3. History of any cardiac diseases,
4. Pregnant and lactating women.
5. History of any thoracic and abdominal tumors,
6. History of any abdominal or thoracic surgery in last 3 months,
7. Smokers
8. Primary lung diseases

COLLECTION OF DATA

A case- control study will be carried out on subjects attending the OPD & IPD of Integral Institute of Medical Science & Research Lucknow.

Diagnosed subjects will be selected on the basis of inclusion and exclusion criteria and who are willing to participate and give written consent form.

PFTs of participants were done by Spirometer i.e. PulmOne in TB and Chest OPD & IPD of Integral Institute of Medical Science & Research, Lucknow.

PROCEDURE

PFT

After taking the anthropometric data, the subjects were informed about the entire maneouver. The subjects were encouraged to perform this maneouver before doing the pulmonary test. The test was performed with the subjects in the sitting position, by using a soft nose clip. The test was repeated three times after the subjects took complete rest and results were in print by using the inbuilt printer which was available in the spirometer. The values of parameters were FVC, FEV1, FEV1/ FVC and PEFR of the best maneouver were taken.

BMI

Height and weight of the subjects will be measured using a standardized height and weight machine. For this, the subjects were in loose clothes and without shoes. Standing height will be measured to the nearest 0.5 cm. Body weight will be recorded in kilograms on an empty bladder and before lunch on a standardized measuring scale. The weight measurement will be recorded to the nearest 0.1 kg.

Revised guidlines for India:

BMI <18.5 kg/m^2 is considered underweight,

BMI <25 kg/m^2 is considered normal,

BMI ≥25 kg/m^2 is considered overweight, and

BMI ≥30 kg/m^2 is considered obese. [21]

GLYCEMIC CONTROL

Patients were diagnosed by using the following criteria: - [4]

1. Fasting blood sugar ≥126 mg/dl

2. Blood Sugar PP ≥ 200 mg/dl

FIGURE-2: PATIENT PERFORMING THE PFT TEST IN OUR RESPIRATORY MEDICINE DEPARTMENT OF INTEGRAL INSTITUTE OF MEDICAL SCIENCE & RESEARCH, LUCKNOW (IIMS&R) (U.P.)

SAMPLE SIZE

The sample size is calculated using the formula – [22]

$$n = \frac{(r+1)}{r} \quad \frac{\sigma^2 (Z_\beta + Z_{\alpha/2})^2}{d^2}$$

n =Sample size

(r+1)/r = ratio of controls to cases

σ^2 = standard deviation of the outcome variable (taken from previous study)

$Z_{\alpha/2}$ = representsthe desired level of statistical significance

Z_β = represent the desired power

d^2 = Expected mean difference

(Reference: Mother article- A.Aparna- India 2013 volume 7 issue 8)

$\sigma = 1.87$

$r = 1$

$Z_\beta = 0.84$

$Z_{\alpha/2} = 1.96$

FEV1/FVC% = (d) =0.99

The sample size for this case control study should be 60.

Type II Diabetes Mellitus = 30

Control Group =30

STATISTICAL ANALYSIS

Statistical analysis is performed by using SPSS-22 statistical software. Comparative study of Pulmonary Function Tests in Type 2 Diabetic and Non-Diabetic patients. The values of parameters (FVC, FEV1, FEV1/FVC% and PEFR) of the best maneouver were taken and the study parameter is calculated by using 'Independent t-test'. The result is presented as Mean ±SD. P value of <0.05 is taken as significant.

OBSERVATIONS

&

RESULTS

RESULTS

The data represented as Mean ± Standard deviation.

We have taken total sixty patients (n = 60) in our study in which 30 were Type 2 Diabetic Mellitus and 30 were Non-Diabetic with age group of 40=60 years. Various studies [8-10-16] done previously for PFTs were having small sample sizes of below 100.

The mean age of Non-Diabetic patients is 49.433 ± 7.536 years, and Median age is 48. The mean age of Type 2 Diabetic Mellitus patients is 48.666 ± 6.353 and Median age is 46. (p- value = 0.335848) (NS)

The mean body mass index of both the groups was not statistically different and both the groups were comparable at baseline. The mean body mass index of the case group was 22.05 ± 3.79 kg/m^2. Median age is 21.9 and the control group was 22.70 ± 3.81kg/m^2. Median age is 22.345 (p- value = 0.256181 NS) (Table: 1)

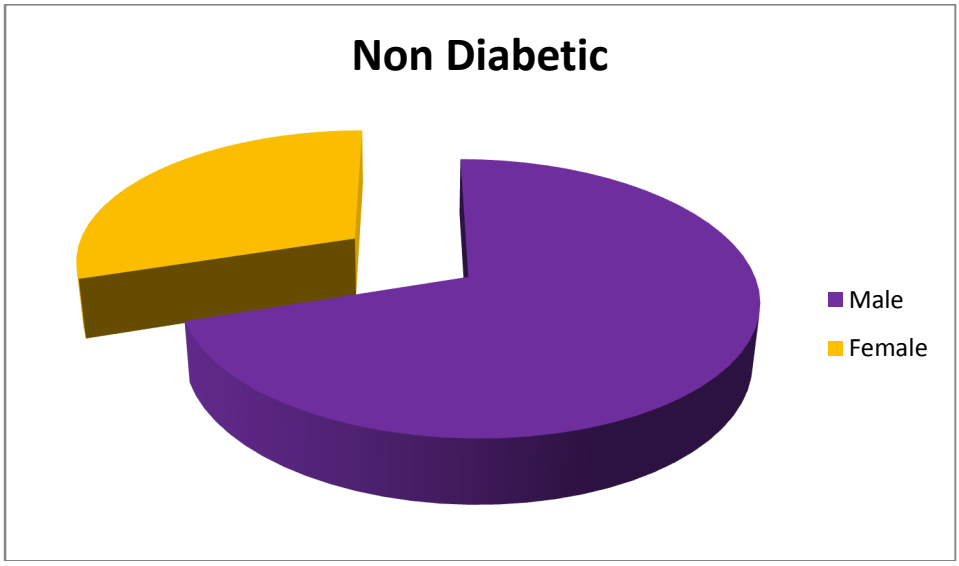
Parameters	Cases (n=30) (Mean±SD)	Control (n=30) (Mean±SD)	p-value
BMI (kg/m^2)	22.05 ± 3.79	22.70 ± 3.81	0.256181 (NS)
AGE (years)	48.66 ± 6.35	49.43 ± 7.53	0.335848 (NS)

Table 1: Comparison of Age and BMI in Type 2 Diabetic Mellitus and Non-Diabetic Group

Out of 30 patients in control group, 21 were males (70%) and 9 were females (30%). Out of 30 patients in cases group, 15 were males and 15 were females (50%-50%). (p-value = 0.113846) [Table: 2] [Figure: 1]

Gender	Diabetic M	Non Diabetic	P - value
Male	15	21	0.113846. (NS)
Female	15	9	
Total	30	30	

Table 2: Distribution of sex between T2DM and Non-diabetic.



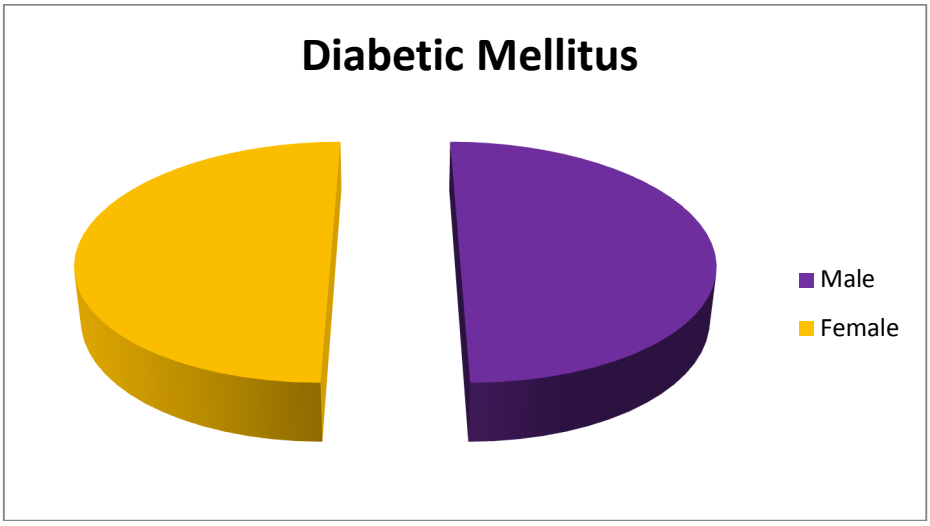


Figure 1: Graphical Distribution of sex between T2DM and Non-diabetic.

FBS and Blood Sugar PP were compared between cases and control. The mean values of Fasting blood sugar level (170.37 ± 56. 68): (89.91 ± 6.17), Blood Sugar Post Prandial (225.24 ± 35.51): (126.69 ± 15.07) were found significantly higher in cases as compared to controls [p value <0.05]. (Table: 3) [Figure: 2]

Parameters	Cases (n=30) (Mean ± SD)	Control (n=30) (Mean ± SD)	p-value
Blood Sugar PP	225.24 ± 35.51	126.69 ± 15.07	< .00001 (HS)
FBS	170.37 ± 56. 68	89.91 ± 6.17	< .00001 (HS)

Table 3: Comparison of Blood Sugar PP and FBS in Type 2 Diabetic Mellitus and Non-diabetic Group

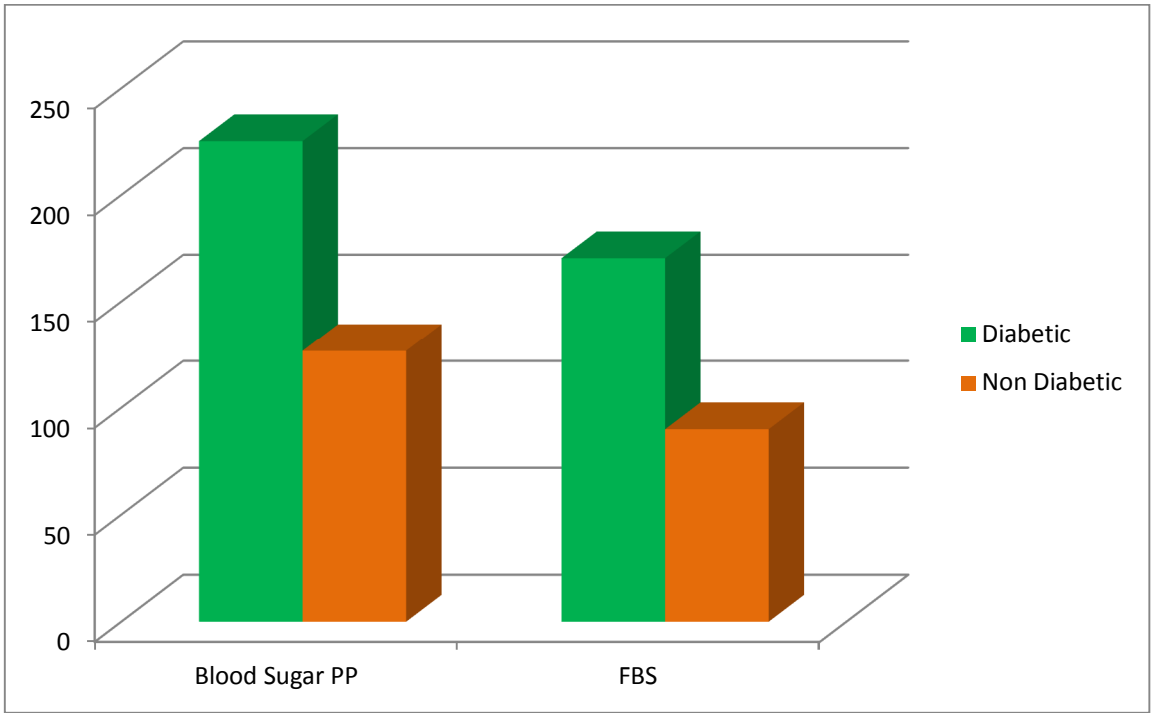


Figure 2: Graphical Comparison of Blood Sugar PP and FBS in Type 2 Diabetic Mellitus and Non-diabetic Group

Mean FVC, FEV1, FEV1/FVC% and PEFR were compared between cases and control (Figure: 3).

Mean FVC was significantly lower in cases as compared to controls (2.42 ± 1.07vs. 4.21 ± 0.421) p -value < 0.00001 (HS) being statistically significant.

Mean FEV1 was significantly reduced in cases as compared to controls (1.75 ± 1.04 vs. 3.321 ±0.44) p -value < 0.00001 (HS) which is statistically significant..

Mean FEV1/FVC % was significantly lower in cases as compared to controls (67.75 ± 15.27 vs78.131 ± 4.98) p - value < 0.00001 (HS) which is statistically significant.

While Mean PEFR is increased in cases as compared to controls (5.38 ± 2.54 vs. 5.36 ± 2.60), p -value 0.489442 (NS) no significant difference was noted. (Table: 4)

Parameters	Cases (n=30) (Mean±SD)	Control (n=30) (Mean±SD)	p-value
FVC (litres)	2.42 ± 1.07	4.21 ± 0.421	< .00001 (HS)
FEV1 (litres)	1.75 ± 1.04	3.321 ±0.44	< .00001 (HS)
FEV1/FVC %	67.75 ± 15.27	78.131 ± 4.98	< .00001 (HS)
PEFR (litres/sec)	5.38 ± 2.54	5.36 ± 2.60	0.489442 (NS)

Table: 4 Comparisons of Pulmonary Function Tests in Type 2 Diabetic Mellitus and Non-diabetic Group

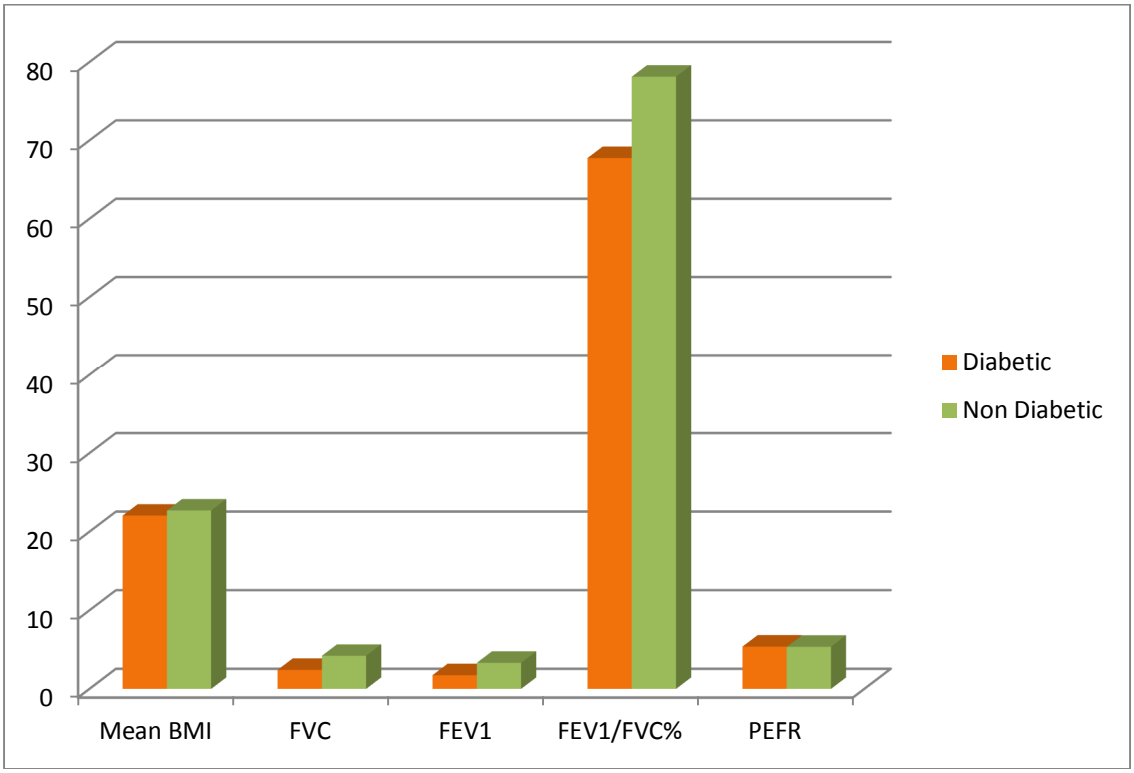


Figure 3: Graphical Comparison of Pulmonary Function Tests in Type 2 Diabetic Mellitus and Non-diabetic

In total 30-30 patients there is difference in BMI and PFTs parameters like FEV1, FVC, FEV1/FVC, and PEFR in terms of male and female of diabetes and non-diabetes patients none of the parameters were statistically significant. [Table: 5-6]

Parameters	Mean BMI	FVC	FEV1	FEV1/FVC%	PEFR	p- value
Diabetic Male	22.18	2.68	1.97	67.53	6.31	0.488481
Diabetic Female	21.92	2.15	1.54	67.97	4.45	

Table 5: Comparison between Diabetic Male and Diabetic Female

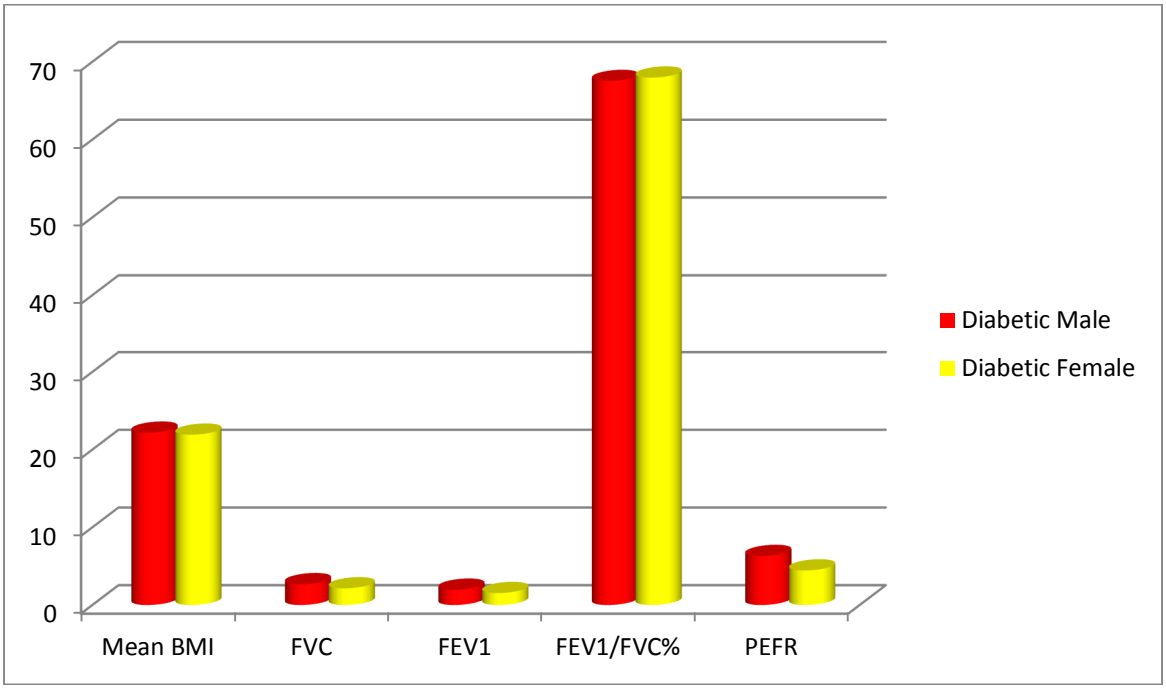


Figure 4: Graphical Comparison between Diabetic Male and Diabetic Female

In Diabetic male group BMI 22.18 ± 3.74 (mean ± SD), FVC 2.68 ± 1.15 (mean ± SD) FEV1 1.97 ± 1.21 (mean ± SD) FEV1/FVC% 67.53 ± 17.62 (mean ± SD) PEFR 6.31± 2.14(mean ± SD)

In Diabetic female group BMI 21.92 ± 3.84 (mean ± SD), FVC 2.15± 0.95(mean ± SD) FEV1 1.54 ± 0.84 (mean ± SD) FEV1/FVC% 67.97 ± 13.14 (mean ± SD) PEFR 4.45± 2.38(mean ± SD) (p-value <0.488481) [Figure: 4]

Parameters	Mean BMI	FVC	FEV1	FEV1/FVC%	PEFR	p- value
Non Diabetic Male	22.19	4.2	3.3	77.6	5.45	
Non Diabetic Female	23.89	4.22	3.35	79.36	5.15	0.487714.

Table 6: Comparison between Non-Diabetic Male and Non-Diabetic Female

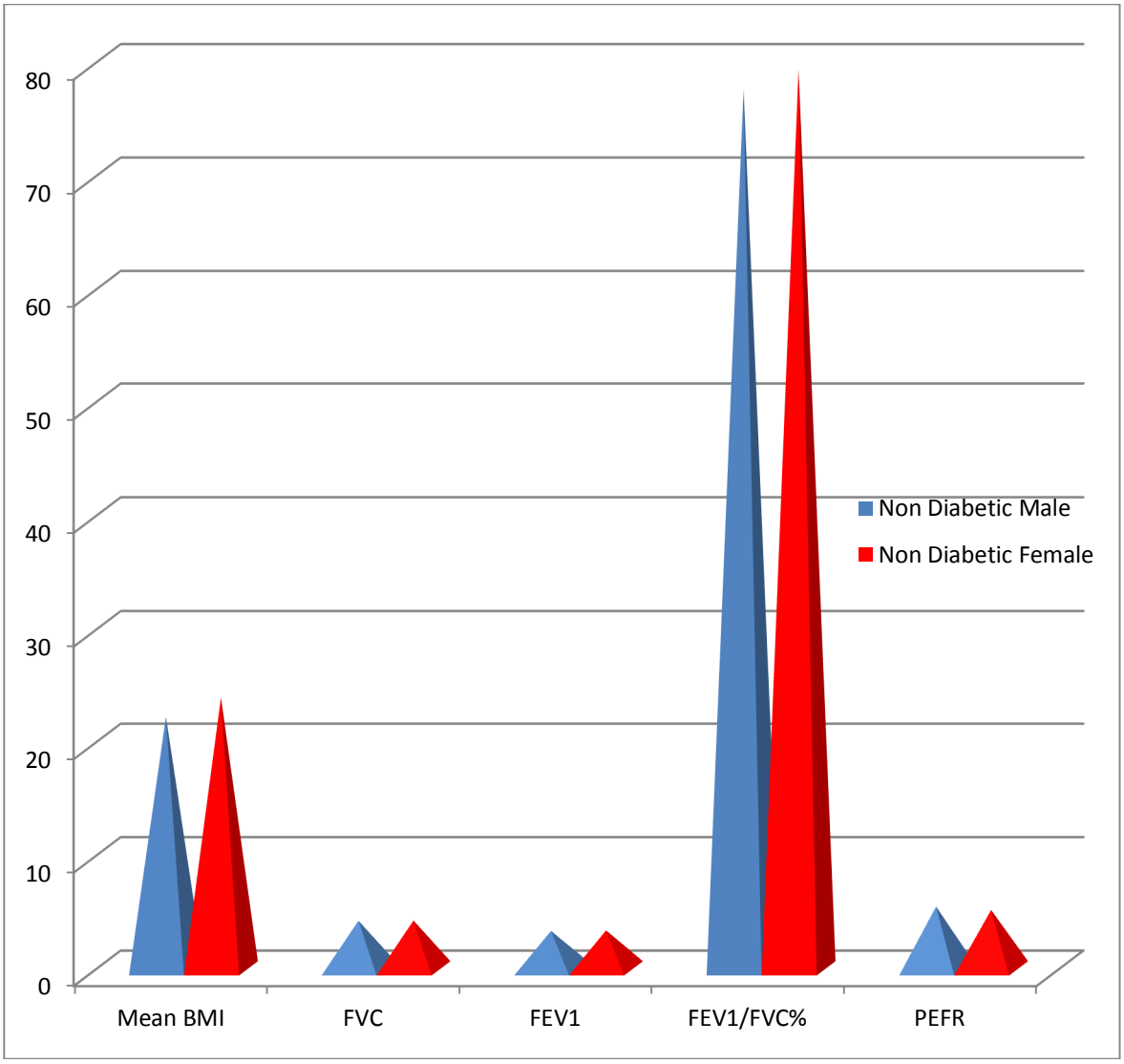


Figure 5: Graphical Comparison between Non-Diabetic Male and Non-Diabetic Female

In Non-Diabetic male group BMI 22.19 ± 3.51 (mean ± SD), FVC 4.20 ± 0.44 (mean ± SD) FEV1 3.30 ± 0.48 (mean ± SD) FEV1/FVC% 77.60 ± 5.82 (mean ± SD) PEFR 5.45± 2.75(mean ± SD)

In Non-Diabetic female group BMI 23.89 ± 4.40 (mean ± SD), FVC 4.22 ± 0.38 (mean ± SD) FEV1 3.35 ± 0.34 (mean ± SD) FEV1/FVC% 79.36 ± 1.60 (mean ± SD) PEFR 5.15± 2.35(mean ± SD) (P <0.487714.)
[Figure: 5]

DISCUSSION

DISCUSSION

The present study is a case- control study comparing the PFTs in T2DM and non-diabetics patients. This study was done to find out the impact of diabetes or the pulmonary functions. Two Groups namely the study & control groups were assigned with equal sex distribution in type 2 DM and in Non-Diabetic it is unequal distributed along with fulfilment of inclusion and exclusion criteria already mentioned.

The mean age of Non-Diabetic patients is 49.433 ± 7.536 years and Type 2 Diabetic Mellitus patients is 48.666 ± 6.353(p- value = 0.335848).
It is similar to the study done by ***Kalappan M et.al (2016)*** where the mean age of the study group among diabetics were 50.71±10.08 and control group was 50.52±10.05 (P = 0.9437). [12]

The mean body mass index of the case group was 22.05 ± 3.79 kg/m^2 and the control group was 22.70 ± 3.81kg/m^2 and sex distribution were found significantly higher in cases as compared to controls.
It is similar to the study published by ***Pawar D, Patil.A et.al (2015)*** where the mean BMI of the cases and control group were (22.91 ± 3.92) (22.15 ± 3.84). Both the studies have similar gender insignificant. [6]

Various biochemical investigations like glycaemic control, as determined by FBS, mean values are (170.37 ± 56. 68): (89.91 ± 6.17), PPBS (225.24 ± 35.51): (126.69 ± 15.07) were found significantly higher in cases as compared to controls.

Other studies conducted by ***Rajani M; Tesema D and Pawar D et.al (2013) (2019) (2015)*** concluded that a higher levels of FBS and PPBS were associated with type 2 diabetic and non- diabetic group have similar findings.[16-13-5]

In our study all the Spirometric values namely FVC, FEV1, FEV1/FVC, were having a mean decrease in diabetic group compared to the control group which was statistically significant proven by getting a P value of <0.05.

Shah et.al (2013) in his study demonstrated that FVC, FEV1 and FEV1/FVC ratio in non diabetics and diabetics as 89.36±9.71 vs. 77.97±12.99, 88.03±6.69 vs. 78.98 ±14.09 and 111.36±10.62 Vs 112.83±9.35 respectively. [7]

However in our study there is mild increased in PEFR of case group which is not statistically significant. Similar to recent study by ***Rajput S et.al*** (2023) PEFR 70.70 (18.50):77.58 (20.63) {p value <0.0823}. [8]

A.Aparna et al (2013),and Shweta, (2013) et.al study detected that almost all the parameters like forced vital capacity, forced expiratory volume at 1st second are decreased resulting in an increase in the ratio in almost all of the patients with uncontrolled diabetes mellitus. [16] As a result, it is obvious that type 2 diabetes mellitus affects the lung, and the lung may be the target organ for damage, and the disease pattern is restrictive in character. [9-11]

The lungs are affected by diabetic microangiopathy. [11] This was evidenced autopsy findings in human diabetic subjects, which showed pulmonary microangiopathy, thickening of alveolar epithelia, pulmonary capillary basal lamina thickening and thickening of alveolar epithelia. Type 2 Diabetes mellitus can cause the development of pulmonary complications due to collagen and elastin changes as well as microangiopathy. [12]

CONCLUSION

CONCLUSION

Present study concluded that the diabetes mellitus is singly associated with the impairment of the pulmonary function test. FVC, FEV1, and FEV1/FVC% are decreased in Type-2 diabetes mellitus compared to controls. PEFR is increased in type-2 diabetes mellitus and also the blood sugar level increases in Type II DM.

It has been determined that the lung is a target organ for diabetes damage and that glycemic exposure is a strong predictor of impaired pulmonary functioning in type II diabetics. Diabetes, especially uncontrolled diabetes, is the major cause of pulmonary problems.

So a comprehensive management will drop the rate of death by a bettered ventilatory function.

Routine spirometry screening in all diabetic cases will help to identify the pulmonary function changes before which is frequently detected late or missed often.

There is significant correlation between age & BMI in type 2 diabetes mellitus & non diabetic patients.

There is significant correlation between PFT in type 2 diabetes mellitus & non diabetic patients.

LIMITATIONS OF THE STUDY

LIMITATIONS OF THE STUDY

1. Few studies showed there is no correlation between blood sugar and PFT's.
2. Sample size is small
3. Patients refusal
4. High gender bias (males > females)

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ANNEXURE – A

INFORMATION SHEET (FOR CASES)

1. I **Ayesha Fatima** M.Sc. third year student of Medical Physiology in IIMS&R Lucknow.
2. I am not associated with your treating doctor panel.
3. There will be no charges /fees/any consideration given or taken for the study.
4. Your identity will be confidential and information and result of your history examination will not be revealed to any other except you if u desire.
5. The study has nothing to do with your treatment and is not going to hamper if you refuse to participate.
6. The study has nothing to do with your current treatment but may improve the knowledge and understanding of disease process and that knowledge may or not be helpful in future.
7. After knowing the all above detail would you like to participate in our study? Yes / No

Name of the patient Signature of the Research Scholar

Signature:

CONSENT FORM

I……age……..W/O,D/O,S/O……Address…… ……. agree to participate in the research work.

Topic **"Comparative study of Pulmonary Function Tests in Type 2 Diabetic and Non-Diabetic patients"**

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

सूचना पत्र (मामलों के लिए)

1. मैं आयशा फातिमा एम.एससी. IIMS&R लखनऊ में मेडिकल फिजियोलॉजी के तीसरे वर्ष का छात्र।
2. मैं आपके उपचार करने वाले डॉक्टर पैनल से संबद्ध नहीं हूं।
3. अध्ययन के लिए कोई शुल्क/शुल्क/कोई विचार नहीं किया जाएगा।
4. आपकी पहचान गोपनीय रहेगी और आपकी इतिहास परीक्षा की जानकारी और परिणाम आपके अलावा किसी और को नहीं बताए जाएंगे, यदि आप चाहें तो।
5. इस अध्ययन का आपके उपचार से कोई लेना-देना नहीं है और यदि आप भाग लेने से इंकार करते हैं तो इससे कोई बाधा नहीं आएगी।
6. अध्ययन का आपके वर्तमान उपचार से कोई लेना-देना नहीं है, लेकिन यह रोग प्रक्रिया के ज्ञान और समझ में सुधार कर सकता है और यह ज्ञान भविष्य में सहायक हो सकता है या नहीं।
7. उपरोक्त सभी विवरणों को जानने के बाद क्या आप हमारे अध्ययन में भाग लेना चाहेंगे? हां नहीं

स्वीकृति/सहमति पत्र (मामलों के लिए)

मै.....उम्र.....पुत्र/पुत्री/पत्नी.....

निवासी.....

अधय्यन विषय - "टाइप 2 मधुमेह और गैर-मधुमेह रोगियों में पल्मोनरी फंक्शन टेस्ट का तुलनात्मक अध्ययन"

मैंने शोध कार्य के विवरण को अच्छी तरह से जाना है और इसके लिए मैं अपनी सहमति देती हूँ/देता हूं।

दिनांक:

रोगियों के हस्ताक्षर/अंगूठे का निशान : शोधार्थी का नाम

गवाह के हस्ताक्षर/अंगूठे का निशान: शोधार्थी के हस्ताक्षर

ANNEXURE – B

INFORMATION SHEET (FOR CONTROL)

1. I **Ayesha Fatima** M.Sc. third year student of Medical Physiology in IIMS&R Lucknow.
2. I am not associated with your treating doctor panel.
3. There will be no charges /fees/any consideration given or taken for the study.
4. Your identity will be confidential and information and result of your history examination will not be revealed to any other except you if u desire.
5. The study has nothing to do with your treatment and is not going to hamper if you refuse to participate.
6. The study has nothing to do with your current treatment but may improve the knowledge and understanding of disease process and that knowledge may or not be helpful in future.
7. After knowing the all above detail would you like to participate in our study? Yes / No

Name of the patient Signature of the Research Scholar

Signature:

CONSENT FORM

I……age……..W/O,D/O,S/O……Address……
……. agree to participate in the research work.

Topic **"Comparative study of Pulmonary Function Tests in Type 2 Diabetic and Non-Diabetic patients"**

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

सूचना पत्र (नियंत्रण के लिए)

1. मैं आयशा फातिमा एम.एससी. IIMS&R लखनऊ में मेडिकल फिजियोलॉजी के तीसरे वर्ष का छात्र।
2. मैं आपके उपचार करने वाले डॉक्टर पैनल से संबद्ध नहीं हूं।
3. अध्ययन के लिए कोई शुल्क/शुल्क/कोई विचार नहीं किया जाएगा।
4. आपकी पहचान गोपनीय रहेगी और आपकी इतिहास परीक्षा की जानकारी और परिणाम आपके अलावा किसी और को नहीं बताए जाएंगे, यदि आप चाहें तो।
5. इस अध्ययन का आपके उपचार से कोई लेना-देना नहीं है और यदि आप भाग लेने से इंकार करते हैं तो इससे कोई बाधा नहीं आएगी।
6. अध्ययन का आपके वर्तमान उपचार से कोई लेना-देना नहीं है, लेकिन यह रोग प्रक्रिया के ज्ञान और समझ में सुधार कर सकता है और यह ज्ञान भविष्य में सहायक हो सकता है या नहीं।
7. उपरोक्त सभी विवरणों को जानने के बाद क्या आप हमारे अध्ययन में भाग लेना चाहेंगे? हां नहीं

स्वीकृति/सहमति पत्र (नियंत्रण के लिए)

मै.....उम्र.....पुत्र/पुत्री/पत्नी.....

निवासी.....

अधय्यन विषय - "टाइप 2 मधुमेह और गैर-मधुमेह रोगियों में पल्मोनरी फंक्शन टेस्ट का तुलनात्मक अध्ययन"

मैंने शोध कार्य के विवरण को अच्छी तरह से जाना है और इसके लिए मैं अपनी सहमति देती हूँ/देता हूं।

दिनांक:

रोगियों के हस्ताक्षर/अंगूठे का निशान : शोधार्थी का नाम

गवाह के हस्ताक्षर/अंगूठे का निशान: शोधार्थी के हस्ताक्षर

ANNEXURE – C
PROFORMA
INTEGRAL INSTITUTE OF MEDICAL SCIENCE & RESEARCH

I. CASE REPORT PERFORMA

- Registration No/Date: OPD_____ IPD_____
- Name (in capital):
- Marital status:
- Address:
- Residence: a) Urban b) Rural
- Mobile no:
- Nationality
- Social/Economical Status:
- Educational level: Uneducated / Metric /Intermediate/Graduate / Postgraduate
- Physical Activity: Sedentary / Moderate / Active
- Occupation:
- Diet: a) Vegetarian

  b) Non-Vegetarian

II. DEMOGRAPHICS

1. Age: _____years
2. Sex: Male_____ Female_____
3. Religion: _____
4. Height: _____cm
5. Weight: _____Kg
6. Body Mass Index (BMI): _____kg/m2

III. FAMILY HISTORY

1. Mother

- a) Mother suffers from Type II Diabetes Mellitus **Yes No Unknown**

2. Father

- b) Father suffers from Type II Diabetes Mellitus **Yes No Unknown**

3. No. of siblings: _____.

- How many of them suffering from Type II Diabetes Mellitus

IV.MEDICAL HISTORY

1. Duration of Type II Diabetes Mellitus _____
2. Diabetic complications: Yes ____ No ___
3. Smoker/tobacco consumer: Yes ____ No _____
4. Alcohol consumer: Yes ____ No _____
5. Treatment: If yes, specify: Yes ____ No
   - Duration of treatment:
6. Patient complications:

V. DIABETIC TEST REPORT

Blood Sugar PP –

FBS –

VI. PULMONARY TEST REPORT

FVC-

FEV1 –

FEV1/FVC% -

PEFR

INSTITUTIONAL ETHICS COMMITTEE (IEC)

IIMS&R INTEGRAL UNIVERSITY, LUCKNOW

IEC/IIMS&R/2023/08

CERTIFICATE

This is to certify that research work entitled **"Comparative Study of Pulmonary Function Tests in Type 2 Diabetic and Non-Diabetic Patients"** submitted by **Ayesha Fatima** 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

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