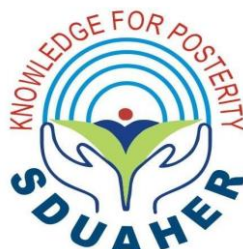


**“CLINICO-RADIOLOGICAL SPECTRUM OF PULMONARY  
TUBERCULOSIS IN DIABETICS AND NON-DIABETIC PATIENTS AT  
TERTIARY CARE CENTRE”**

**DR. K. SREENATH REDDY**



**DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER  
EDUCATION AND RESEARCH, KOLAR, KARNATAKA**

**In partial fulfillment of the requirements for the degree of**

**DOCTOR OF MEDICINE**

**IN**

**GENERAL MEDICINE**

**GUIDE:**

**DR B.N.RAGHAVENDRA PRASAD** M.B.B.S, MD (MEDICINE)

**HOU & PROFESSOR**

**DEPARTMENT OF GENERAL MEDICINE**

**SDUMC, KOLAR**



**DEPARTMENT OF GENERAL MEDICINE,  
SRI DEVARAJ URS MEDICAL COLLEGE, TAMAKA,  
KOLAR-563101**

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Date:

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**DR. K. SREENATH REDDY**

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Date:

**SIGNATURE OF THE GUIDE**

Place: Kolar.

**DR. B.N RAGHAVENDRA PRASAD**

Professor and HOU  
Department of Medicine  
Sri Devaraj Urs Medical College,  
Tamaka, Kolar.

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**DR. RAVEESHA. A, MD.**

Professor and HOD,  
Department of Medicine,  
Sri Devaraj Urs Medical College,  
Tamaka, Kolar.

**DR. P. N. SREERAMULU**

Principal,  
Sri Devaraj Urs Medical  
College, Tamaka, Kolar.

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Place: Kolar.

**Member Secretary**

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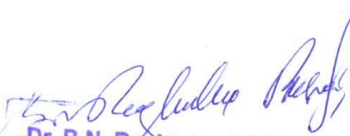


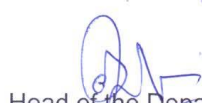


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Dr. B. N. Raghavendra Prasad  
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KMC No: 21051  
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## ABSTRACT

**Background:** Diabetic individuals have three times more risk of developing tuberculosis. Clinical presentation and response to treatment both have a different course in diabetic individuals in comparison with non-diabetes individuals. The aim of the study was to determine the clinic - radiological spectrum of pulmonary tuberculosis in diabetics and non-diabetic patients.

**Methods:** The study was conducted in the department of General Medicine at R.L. JALAPPA hospital, Kolar. The study included two groups; one group consisted of diabetic patients with pulmonary tuberculosis, and another group comprised of non-diabetic pulmonary tuberculosis patients. Informed consent was obtained from all participants.

**Results:** A total of 163 subjects were included in the final analysis, with 79 participants in the diabetic group and 84 participants in the non-diabetic group. The radiological appearance was Cavitory for 19% participants, Consolidation for 39.2% participants, Fibro cavitory for 13.9% participants in the diabetic group. Out of 84 participants in the non-diabetic group, the radiological appearance was Cavitory for 10.7% participants, Consolidation for 29.8% participants, Fibro cavitory for 9.5% participants

**Conclusion:** This study found clinical presentation symptoms almost similar between diabetic patients with tuberculosis and non-diabetic patients with tuberculosis. The radiographic spectrum of tuberculosis was found to be different in diabetic patients. Diabetic patients were found to have more cavitation and involvement of lower lobe of lung as against upper lobe in non-diabetic patients

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## LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
AIDS	Acquired immunodeficiency syndrome
CI	Confidence interval
DM	Diabetes mellitus
DST	Dexamethasone suppression test
EPTB	Extrapulmonary Tuberculosis
HIV	Human immunodeficiency virus
IQR	Interquartile range
MODS	Microscopic-observation drug-susceptibility assay
MTB	Mycobacterium tuberculosis
PTB	Pulmonary tuberculosis
RIF	Right iliac fossa
TB	Tuberculosis

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# INTRODUCTION



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## INTRODUCTION:

Worldwide, tuberculosis remains a global public health problem. Pulmonary Tuberculosis is an airborne disease caused by *Mycobacterium tuberculosis* that usually affects the lungs leading to severe coughing, fever, and chest pains. One-third of the world's population is infected with *Mycobacterium Tuberculosis*, and depending on the interaction of the epidemiological triad about 10% of them are at risk of developing the active form of the disease in their lifetime.

Globally, tuberculosis is one among the top 10 causes of mortality. In the year 2017, “10.4 million cases” of TB were reported and 1.8 million death according to the World Health Organization. India accounts for 24% of the total global TB burden and 29% of mortality. In India, the prevalence of DM in 2016 was 61 million.<sup>1</sup> In India, diabetes accounts for 14.8% of pulmonary TB and 20.2% of smear-positive TB in the year 2000.<sup>2</sup>

Age, immune status, immunization status to the bacillus Calmette-Guerin, co-existing diseases, the virulence of the infecting organism and host-microbe interaction are the factors that determine the clinical manifestations of tuberculosis. Cough, sputum, hemoptysis, breathlessness, weight loss, anorexia, fever, malaise, wasting, and terminal cachexia are the traditional symptoms and signs of pulmonary tuberculosis. The commonest clinical presentation in tuberculosis patients is the cough. The frequency of fever in tuberculosis patients is identified between 37 to 80%.<sup>3, 4</sup> The other common symptoms involved in tuberculosis are the loss of appetite, weight loss, weakness, night sweats and malaise.<sup>5</sup> VALavi SM. et al<sup>6</sup>, performed a study in which the sputum, hemoptysis and dyspnea were identified more prominent in TB with DM (69.4%, 33.4%, 44.5%) as compared to TB without DM (36.6%, 9.8%, 20.5%).



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The peripheral blood polymorphonuclear leukocyte count and anemia are the most frequent hematologic manifestations. The prevalence of hematologic manifestations is identified with 10% of each.<sup>7, 8</sup> The production of an antidiuretic hormone-like substance in the affected lung tissue can cause hyponatremia in 11% of the patients with tuberculosis.<sup>9, 10</sup> HIV infection, alcoholism, drug abuse, chronic renal failure, diabetes mellitus, neoplastic diseases are serious disorders associated with tuberculosis.<sup>5</sup>

Human immunodeficiency virus, diabetes mellitus, smoking and malnutrition are the risk factors that can lead to tuberculosis mortality. The risk of TB among DM patients is three times higher as compared to those without DM.<sup>1</sup> The most commonly used methods for the diagnosis of pulmonary TB are the direct sputum smear microscopy and mycobacterial culture.<sup>11</sup> The diagnosis of TB is confirmed by performing the culture of *M. tuberculosis*. It is also required for drug susceptibility testing. Mycobacterial culture is considered as much more sensitive as compared to the sputum smear. Mycobacterial culture on the liquid medium is faster (10 to 14 days) as compared to that on solid medium (4-8 weeks).

Chest radiography also plays a major role in the screening and diagnosis of pulmonary TB. Poorly defined nodules, linear opacities, focal or patchy heterogeneous consolidation involving the apical and posterior segments of upper lobes and the superior segments of lower lobes were the typical radiographic findings of pulmonary TB in immunocompetent hosts.<sup>12, 13</sup> In a cross-sectional hospital-based observational study conducted by Das S, et al<sup>14</sup>, in which the cavitory lesion, infiltration, consolidation, non-homogenous opacity and military shadow were the X-ray pattern of TB patients with 41.66%, 25%, 18.3%, 13.3% and 1.6% in who were suffering from diabetes mellitus.

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Chauhan J et al<sup>15</sup>, conducted a study in 50 DM patients in which 24% of the patients had chest x-ray with lesions whereas, 76% of the patients have no lesion on chest X-ray. Out of 12 chests, X-ray positive patients, sputum positive and sputum negative results were identified with 75% and 25%. In controlled DM, 25% of the patients have chest X-ray positive, and 33.33% of patients had sputum positive result. Whereas, in uncontrolled DM, 75% of patients had chest X-ray positive, and 66.66% patient had sputum positive results.

Management of TB usually involves an intensive initial 2-month phase that is followed by a slower 4- to 6-month continuation phase. Isoniazid, rifampin, pyrazinamide and either ethambutol or streptomycin are the main anti-tuberculosis drugs used in the chemotherapy of TB.

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## **NEED OF THE STUDY:**

Although diabetes mellitus is an accepted risk factor for developing active TB disease, the association between diabetes mellitus and tuberculosis clinical characteristics, including TB disease presentation and TB treatment outcomes were limited in data. The association between diabetes and TB drug resistance and treatment outcomes were identified in a few studies only. Currently, due to converging epidemic of both communicable and non-communicable diseases, both the “tuberculosis and diabetes” are of global public health importance. About 95% of patients with tuberculosis and 70% of patients with diabetes mellitus live in low and middle-income countries. As a result, both of them are increasingly occurring together. The risk of tuberculosis is two to five times greater in patients with diabetics as compared to non-diabetics. Many studies depict that pulmonary tuberculosis in a patient with type 2 DM have some different and specific presentations. The aim of the study was to determine the clinic - radiological spectrum of pulmonary tuberculosis in diabetics and non-diabetic patients

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# AIMS & OBJECTIVES



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## **AIMS AND OBJECTIVES:**

1. To study the clinical spectrum of pulmonary tuberculosis in Diabetic and non-Diabetic patients.
2. To study the radiographic spectrum of pulmonary tuberculosis in Diabetic and non-Diabetic patients.
3. To study the difference in presentation among Diabetic and non-Diabetic patients.

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# REVIEW OF LITERATURE



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## **REVIEW OF LITERATURE:**

### **1. Pulmonary Tuberculosis**

#### **a) Definition**

Pulmonary Tuberculosis is an airborne disease caused by *Mycobacterium tuberculosis* that usually affects the lungs leading to severe coughing, fever, and chest pains.

#### **b) Clinical presentation**

Age, immune status, immunization status to the bacillus Calmette-Guerin, co-existing diseases, the virulence of the infecting organism and host-microbe interaction are the factors that determine the clinical manifestations of tuberculosis. Systematic symptoms can be produced by tuberculosis involving any site. The frequency of fever in tuberculosis patients is identified between 37 to 80%.<sup>3, 4</sup> The other common symptoms involved in tuberculosis are the loss of appetite, weight loss, weakness, night sweats and malaise.<sup>5</sup>

The peripheral blood polymorphonuclear leukocyte count and anemia are the most frequent hematologic manifestations. The prevalence of hematologic manifestations is identified with 10% of each.<sup>7, 8</sup> The production of an antidiuretic hormone-like substance in the affected lung tissue can cause hyponatremia in 11% of the patients with tuberculosis.<sup>9, 10</sup>

HIV infection, alcoholism, drug abuse, chronic renal failure, diabetes mellitus, neoplastic diseases are serious disorders associated with tuberculosis. The commonest clinical presentation in tuberculosis patients is the cough. It may be nonproductive initially but can produce sputum once the inflammation and tissue necrosis progressed.<sup>5</sup>

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Hemoptysis can arise from tuberculosis bronchiectasis, rupture of a dilated vessel in the wall of a cavity, a bacterial or fungal infection in a cavity or an erosion into the airway.<sup>16, 17</sup> Whereas, the pleuritic pain can be caused by the inflammation of the lung parenchyma that is adjacent to a pleural surface. Rales or crackles can be heard in the area of involvement and consolidation can be indicated by the bronchial breathing.<sup>5</sup> Cough, sputum, hemoptysis, breathlessness, weight loss, anorexia, fever, malaise, wasting, and terminal cachexia are the traditional symptoms and signs of pulmonary tuberculosis.

**c) Epidemiology- global, India,**

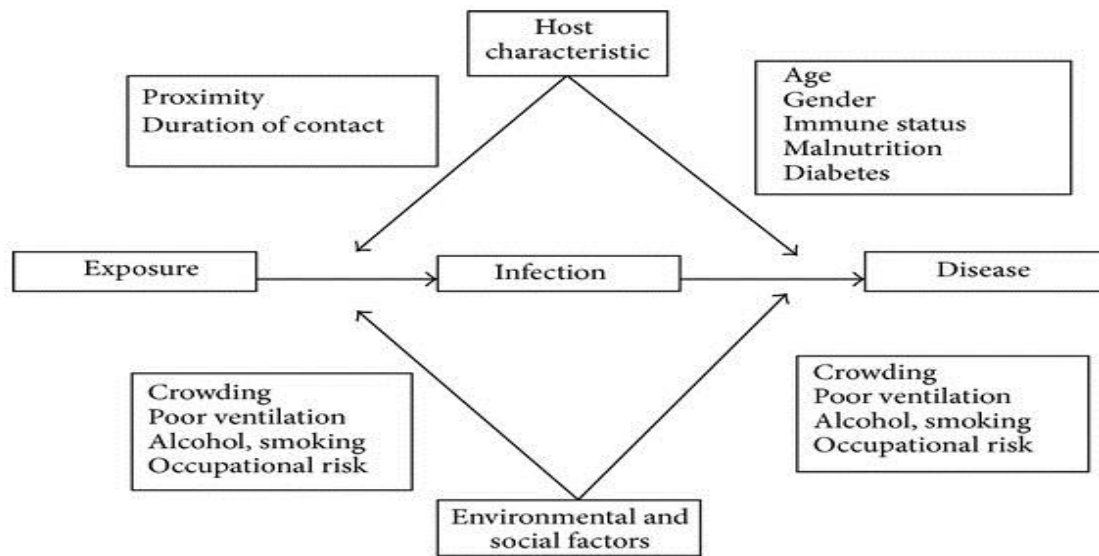
One-fourth of the total tuberculosis burden is contributed by India. The estimated annual global incidence of tuberculosis in the year 2016 is 10.4 million cases. In India, in the same year, approximately 2.8 million new cases were identified.<sup>18</sup> Worldwide, India accounts for around 27% of all incident cases. In India, the estimated incidence of tuberculosis in the year 2017 is 204/100,000 population. In 2018, the estimated incident cases of tuberculosis are around 10 million.<sup>19</sup>

**d) Causes, risk factors, pathogenesis**

Pulmonary tuberculosis is an infectious disease caused by *Mycobacterium tuberculosis*.<sup>20</sup> In people living with HIV, the risk of developing TB is 30 times higher as compared to those without HIV infection. The risk of immune reconstitution inflammatory syndrome and death are high in TB patients with advanced AIDS. Diabetes mellitus, malnutrition, pre-existing pulmonary conditions like chronic obstructive pulmonary disease and asthma and smoking, indoor air pollution and harmful alcohol use are also the risk factors associated with TB.<sup>21-23</sup>



**Figure 1: Risk factors for pulmonary tuberculosis.<sup>24</sup>**



The droplet nuclei containing the *M. tuberculosis* is transmitted from person to person mainly through coughing. The host immunity adequately limits further multiplication of bacilli; hence the initial infection is clinically silent in most of the cases.<sup>25</sup> The immunity against the tuberculosis bacilli is not adequate in 5% of the infected individuals. The clinically active disease that develops within 1 year of infection is called as the progressive primary tuberculosis.<sup>26</sup>

Immunosuppression, advanced age or a large inoculation of mycobacteria are the risk factors for progressive primary disease. Latent TB infection is tuberculosis that remains clinically and microbiologically latent for many years. Positive tuberculin skin test, interferon  $\gamma$  release assay or the presence of calcification at the site of primary lung infection or in regional lymph nodes are used for the detection of latent TB infection.

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Endogenous reactivation or re-infection by new strains can develop in around 5% of the patients with latent TB infection after many years of the initial infection identification. The risk of post-primary TB development can be increased by the presence of suppression of cellular immunity by HIV infection, tumor necrosis factor- $\alpha$  inhibitors, glucocorticoids, organ or hematologic transplantation and end-stage renal disease.<sup>27</sup>

#### **e) Diagnosis and management**

##### **Sputum smear microscopy:**

The most commonly used methods for the diagnosis of pulmonary TB are the direct sputum smear microscopy and mycobacterial culture.<sup>11</sup> Conventional light microscopy of Ziehl-Neelsen stained smears and fluorescence microscopy are also used for the diagnosis of TB. But the sensitivity of smear microscopy is low. On the other hand, fluorescence microscopy is more sensitive than Ziehl-Neelsen staining and takes less time, but has high associated maintenance costs. The smear microscopy is identified with low sensitivity.<sup>27</sup>

Fluorescence microscopy is identified with high sensitivity and also less time consuming as compared to the Ziehl-Neelsen staining. When compared to the conventional methods, the light-emitting diodes microscopy is observed with more sensitivity.<sup>28, 29</sup> Low sensitivity and inability to differentiate *M. tuberculosis* and nontuberculous mycobacteria are the two drawbacks of sputum smear microscopy.<sup>27</sup>

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### **Mycobacterial culture:**

The diagnosis of TB is confirmed by performing the culture of *M. tuberculosis*. It is also required for drug susceptibility testing. Mycobacterial culture is considered as much more sensitive as compared to the sputum smear. Mycobacterial culture on the liquid medium is faster (10 to 14 days) as compared to that on solid medium (4-8 weeks). BancTec Mycobacterial Growth Indicator Tube 960 or BacT/ALERT are the automatic detection tools used in mycobacterial culture. It requires a stable electricity supply, technical support and expensive reagents.<sup>27</sup>

The susceptibility results for streptomycin, isoniazid, rifampicin, and ethambutol kit and pyrazinamide kit are provided by the validation of BancTec MGIT 960. Sensitivity and specificity of BancTec MGIT 960 for detecting rifampin resistance were 99% to 100% and 97% to 100%. Whereas, for isoniazid resistance were 95% to 100% and 100% respectively. Median turnaround time for the SIRE kit and PZA kit was 5.5 to 8.3 days and 5 to 8.2 days. The sensitivity and specificity of BacT/ALERT system for detecting rifampin resistance were 99% to 100% and 92% to 100% While for isoniazid resistance were 100% and 88% to 100% respectively. The SIRE and PZA kits had a median turnaround time of 5 to 8.2 and 5 to 7.4 days, respectively.<sup>30</sup>

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**Microscopic-observation drug-susceptibility assay (MODS):**

MODS is considered as an accurate, inexpensive, liquid culture-based diagnostic test. It is used for the rapid screening of patients suspected with multidrug-resistant.<sup>31</sup> The sensitivity and specificity of MODS for the rifampicin resistance were 98.0% and 99.4%. In case of isoniazid resistance with a 0.1 µg/mL cutoff, pooled sensitivity and specificity were 97.7% and 95.8% whereas with a 0.4 µg/mL cutoff, sensitivity and specificity were 90.0% and 98.6% respectively.<sup>32, 33</sup>

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**Nucleic acid amplification testing, Xpert MTB/RIF assay and Line probe assay for diagnosis of drug resistance were the molecular methods used for the diagnosis of TB.**

**Imaging studies:**

**Chest radiography:** It plays a major role in the screening and diagnosis of pulmonary TB. Poorly defined nodules, linear opacities, focal or patchy heterogeneous consolidation involving the apical and posterior segments of upper lobes and the superior segments of lower lobes were the typical radiographic findings of pulmonary TB in immunocompetent hosts.<sup>12, 13</sup> In patients with active disease the radiographs can show normal, mild or nonspecific findings. Chest radiographs show miliary TB, hilar or mediastinal lymphadenopathy and pleural effusion in immunocompromised hosts.<sup>34</sup>

Computed tomography: It is used for the detection and characterization of subtle parenchymal disease and mediastinal lymphadenopathy. Pulmonary TB is correctly diagnosed in 91% of patients and is correctly excluded in 76% of patients through the computed tomography.<sup>35</sup>

**Table 1: Characteristic CT findings of pulmonary TB.<sup>27</sup>**

Site	CT findings
Parenchyma	
Active TB	Centrilobular nodules, tree-in-buds pattern, patchy or lobular consolidation, cavity, CT galaxy signa), lower lobe consolidation.
Tuberculoma	Smoothly marginated nodule, no enhancement or ring-like enhancement
Miliary TB	1–3 mm diameter nodule with random distribution, thickening of interlobular septa or intralobular interstitial lines
Lymph node	Central areas of low attenuation with peripheral rim enhancement
Airway	Circumferential wall thickening and luminal narrowing, with the involvement of a long segment of the bronchi
Pleura	Pleural effusion with smooth thickening of the visceral and parietal pleural surfaces

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Whether the individual is in the latent or active stage and on his or her probability of risk are the factors that determine the course of TB treatment. Treatment of TB usually involves an intensive initial 2-month phase that is followed by a slower 4- to 6-month continuation phase. Isoniazid, rifampin, pyrazinamide and either ethambutol or streptomycin are the main anti-tuberculosis drugs used in the chemotherapy of TB. Treatment for TB can last from 6 to 9 months or even up to 20 months.

## **2. Pulmonary tuberculosis in diabetes mellitus**

### **a. Epidemiology**

Worldwide, 415 million people were diagnosed with diabetes mellitus in the year 2015 by the International Diabetes Federation, and by 2040 the number is expected to rise to 642 million.<sup>36</sup> The low- and middle-income countries were identified with 95% of TB cases, and also the same countries were identified with more than 70% of patients with DM.<sup>37</sup> In India, there are 62.4 million people with Type 2 diabetes and 77 million people with pre-diabetes as per the Indian Council of Medical Research-National study. By the year 2030, these numbers are expected to increase to 101 million.<sup>37</sup>

The prevalence of known Type 2 DM in urban areas and known T2DM in peri-urban/slum areas were 7.3% and 3.2% as per the nation-wide surveillance study of DM.<sup>38</sup> In India, diabetes accounts for 14.8% of pulmonary TB and 20.2% of smear-positive TB in the year 2000.<sup>2</sup> In Indian population Raghuraman S, et al<sup>39</sup>, conducted a cross-sectional study in which the prevalence of diabetes in tuberculosis patients was identified to be 29% (known diabetics - 20.7% and new Diabetes cases - 8.3%).

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### **b. Clinical presentation and clinical spectrum in detail**

In a population of 148 patients Alavi SM et al<sup>6</sup>, conducted a study in which sputum, hemoptysis and dyspnea were more frequent in TB patients with DM with 69.4%, 33.4%, 44.5%. Similarly, the rate of sputum smear positivity in TB with DM was also higher, with 66.6%. Anusuya M. et al<sup>40</sup>, performed a study in which anorexia, cough and loss of weight were the major clinical presentations identified in TB patients with DM with 82%, 77% and 44% respectively. Sputum positivity was identified high in those who aged less than 40 years and in those more than 40 years with 86% and 54% respectively. In a Cross-sectional study conducted by Chaudhary HS. et al<sup>41</sup>, coughs, fever, anorexia, loss of weight, dyspnea, hemoptysis, night sweats, chest pain, were the symptoms identified in Tb patients with DM with 94.55%, 90%, 52.73%, 50.91%, 43.64%, 21.81%, 17.27% and 7.27% respectively.

### **c. Radiological presentation and Radiographic spectrum**

Alavi SM et al<sup>6</sup>, performed a study in which the chest x-ray revealed that the cavitation and reticulonodular pattern were more common in TB with DM with 55.5% and 22.2% respectively. In a population of 220 TB patients with DM Chaudhary HS. et al<sup>41</sup>, conducted a cross-sectional study in which cavity with nodule was identified in 36.36% of patients, and the normal chest x-ray was normal in 2.72% of patients. Anusuya M. et al<sup>40</sup>, conducted a study in TB patients with DM in which the lower lobe involvement, right side involvement, left side involvement were identified with 34%, 39%, 30% and 31% respectively. Cavity with nodule was present in 36.36% of patients and patients have normal chest x-ray is seen in 2.72% of patients.

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In a cross-sectional hospital-based observational study conducted by Das S, et al.<sup>14</sup>, in which the cavitory lesion, infiltration, consolidation, non-homogenous opacity and miliary shadow were the X-ray pattern of TB patients with 41.66%, 25%, 18.3%, 13.3% and 1.6% in who were suffering from diabetes mellitus respectively. X-Ray abnormality involving only a single zone, 2 zones, 3 zones and 4 zones were observed with 33%, 25%, 15% and 6.6% respectively.

### **3. Clinico – Radiological Spectrum Of Pulmonary Tuberculosis In Diabetic Vs Non-Diabetic**

#### **a) Compare the prevalence of pulmonary TB in non-DM or (general) vs in DM**

Worldwide, the estimated prevalence of TB annually is around 9.6 million, and of them, 1 million have both TB and DM. Around 17% of the world's burden of TB accounts with China and with a very large burden of DM, with nearly 100 million people affected. In India, in the year 2011, there were 61.3 million cases with DM and 1.98 million people with developing TB.<sup>42</sup> Diabetic patients were more prone to develop pulmonary TB with 87% as compared to non-diabetic TB patients, with 59%.<sup>43</sup>

#### **b) Compare mortality rates in pulmonary TB with diabetic vs pulmonary TB in non-diabetic**

The mortality rate in TB patients with DM was 7.5% which was higher as compared to the TB only and DM only groups with 1% and 2% respectively.<sup>43</sup>



**Table 2: The effect of diabetes mellitus on mortality in patients treated for tuberculosis in various studies.<sup>44</sup>**

Studies	Population	Outcome variables and findings (diabetes vs non-diabetes)
Mboussa et al. <sup>45</sup>	32 cases, 100 controls	25.1% vs 8%
Lindoso et al. <sup>46</sup>	416	The proportion of patients with TB-related death who had diabetes mellitus: 16%
Wang et al. <sup>47</sup>	217	OR 2.56 (1.08–6.03), AOR 5.5 (2.27–13.5), adjusting for age and sex
Dooley et al. <sup>48</sup>	297	OR 2.0 (0.74–5.2), AOR 6.5 (1.1–38.0), adjusted for HIV status, age, weight, and foreign birth.
Oursler et al. <sup>49</sup>	139	HR 4.8 (2.0–11.6), AHR 6.7 (1.6–29.3), adjusted for renal disease, COPD, HIV infection, and age

### c) Clinical presentation and clinical spectrum

In the study performed by Paralija B, et al<sup>50</sup>, the most common symptom in PTB patients with diabetes mellitus and PTB patients without diabetes mellitus were cough. Hemoptysis was identified in diabetic patients and non-diabetic patients with 29.9% and 13.4%. Hence the study concludes that the more severe clinical presentation can be observed in TB patients with DM. Alavi SM., et al<sup>6</sup> performed a study in which the sputum, hemoptysis and dyspnea were identified more prominent in TB with DM (69.4%, 33.4%, 44.5%) as compared to TB without DM (36.6%, 9.8%, 20.5%). The rate of sputum smear positivity in TB with DM was 66.6% whereas, TB without DM was 47.3%.

Table 3: The effect of diabetes mellitus on the conversion of sputum smear or culture from positive to negative in patients treated for tuberculosis in various studies.<sup>44</sup>

Study	Outcome variables and findings (diabetes vs non-diabetes)
Singla et al. <sup>51</sup> (692 patients)	2-month sputum smear conversion: 83.8% vs 90.7%; 3-month sputum smear conversion: 98.9% vs 94.7%
Alisjahbana et al. <sup>52</sup> (634 patients)	The proportion with positive microscopic examination of sputum after 2 months of treatment: 18.1% vs 10%.
Banu Rekha et al. <sup>53</sup> (190 patients)	Conversion to negative after completion of intensive-phase TB treatment: sputum smear, 58% vs 61%; sputum culture, 86% vs 88%
Guler et al. <sup>54</sup> (737 patients)	Time to culture conversion: 67 days vs 55 days.
Restrepo et al. <sup>55</sup> (469 patients)	Time to culture conversion: 42 days vs 37 days
Dooley et al. <sup>48</sup> (207 patients)	The median time to sputum culture conversion: 49 days vs 39 days, Proportion converting culture to negative by 2 months: 70% vs 69%.
Maalej et al. <sup>56</sup> (142 patients)	Time to culture conversion: 43 (SD 27) days vs 28 (SD 20) days.

#### d) Radiological presentation and Radiographic spectrum

The chest x-ray showed that the cavitation and reticulonodular pattern were more frequent in TB with DM (55.5%, 22.2%) as compared to TB without DM (31.2%, 8%) in Alavi SM et al<sup>6</sup>, study. Among the DM patients, X-ray lesions were identified in the upper, middle and lower of the lung with 25%, 41.67% and 33.33% respectively. Uncontrolled DM was identified with more X-ray positive patient (66.67%) as compared to the controlled DM 33.33%. Chauhan J et al.,<sup>15</sup> conducted a study in 50 DM patients in which 24% of the patients had chest x-ray with lesions whereas, 76% of the patients have no lesion on chest X-ray. Out of 12 chests, X-ray positive patients, sputum positive and sputum negative results were identified with 75% and 25%. In controlled DM, 25% of the patients have chest X-ray positive, and 33.33% of patients had sputum positive result. Whereas, in uncontrolled DM, 75% of patients had chest X-ray positive, and 66.66% patient had sputum positive results.

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Paralija B et al<sup>50</sup>, conducted a comparative study in which the extensive forms of PTB was identified in 41.2% PTB patients with diabetes mellitus and 24.8% PTB patients without diabetes mellitus.

Krishna V et al<sup>57</sup>, conducted a cross-sectional observational study in 50 tuberculosis patients with diabetes mellitus. The aim of the study was to determine the clinic-radiological pattern of pulmonary tuberculosis with diabetes mellitus. The majority of the patients were males with a male: female ratio of 7:3. The major complaints were hemoptysis and weight reduction. Involvement of the lower lung field was identified in 56% of the cases. Whereas, the bilateral involvement was identified in 18% of the patients. DM was detected for the first time in 27 patients with TB. Among them, high bacillary load (sputum >2+) was identified in 20 patients, and 15 patients required insulin. Around 18% of the patients were observed with cavitary lesions. Through the present study, it was concluded that patients with diabetes mellitus are at high risk of getting infected with tuberculosis.

Chaya B et al<sup>58</sup>, performed a cross-sectional study in 50 participants. The purpose of the study was to evaluate the clinic radiological correlation between diabetes mellitus and tuberculosis. Majority of the study participants were males with 72%, followed by females with 28%. The incidence of TB was high in patients aged >50 years, with a peak incidence in 51-60 & 61-70. The study results revealed that 52.8 and 55.6 years were the mean age for males and females. Cough, fever, anorexia, loss of weight, dyspnea, hemoptysis, chest pain, night sweats were the symptoms identified in the study population with 92%, 80%, 58%, 56%, 42%, 20% and 20% respectively. Mean FBS and PPBS were 241 mg/dl and 316 mg/dl, respectively. Cavitation lesions and non-homogenous opacities were observed with 38% and 22% respectively. The present study concluded the association between severe hyperglycemia and the development of pulmonary TB.

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Magee MJ. et al<sup>59</sup>, conducted a study in TB patients. The aim of the study was to determine the relationship between DM and TB disease severity during the diagnosis of TB and poor TB clinical outcomes. The study results revealed that patients with TB and DM were more prone to identify with higher sputum smear grade as compared to TB patients who are not having diabetes. The estimated hazard of “sputum culture” conversion was lower in MDR TB patients with DM than those patients without DM. The study concluded that TB patients with DM can have more severe TB disease at the time of clinical presentation.

Chaudhary HS. et al<sup>41</sup>, performed a Cross-sectional study in 220 patients. The aim of the study was to identify various pulmonary manifestations in TB patients with DM. Majority of the patients were males with 70%. Cough, fever, anorexia, loss of weight, dyspnea, hemoptysis, night sweats and chest pain were the symptoms identified with 52.73%, 50.91%, 43.64%, 21.81%, 17.27% and 7.27% respectively. Cavity with nodule was identified in 36.36% of cases. Chest x-ray was normal in 2.72% of patients. Early diagnosis and properly monitored treatment regimen should be encouraged.

Zaiyad GH. et al<sup>60</sup>, conducted a cross-sectional study in 220 TB patients. The purpose of the study was to identify the association between pulmonary tuberculosis and diabetes mellitus. The mean age in patients with TB and DM and in those without DM were 59.1 and 32.0 years, respectively. TB with DM was observed in 9.55% of the cases. TB patients with DM and those without showed differences in clinical features and laboratory investigation results. Early screening of TB for DM can help in providing appropriate care and improving clinical outcome.

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Das S et al<sup>14</sup>, conducted a cross-sectional hospital-based observational study. The aim of the study was to evaluate the X-Ray Pattern of Patients of Pulmonary Tuberculosis with Diabetes Mellitus. Cavitory lesion, infiltration, consolidation, non-homogenous opacity and military shadow were identified in the X-ray with 41.66%, 25%, 18.3%, 13.3% and 1.6% respectively. X-Ray abnormality involving only a single zone was observed in 33% of cases. Whereas, abnormality in 2 zones, 3 zones and 4 zones were identified with 25%, 15% and 6.6% respectively. The study concluded that the association between the elderly population and the development of lower lung field involvement.

Shahi RK. et al<sup>61</sup>, performed a study in 105 patients. The aim of the study was to identify various presentations in tuberculosis and T2DM patients. The mean age of TBDM group and mean age were  $51.2 \pm 8.05$  and  $39.5 \pm 9.2$  years, respectively. The mean duration of T2DM was  $4.21 \pm 1.86$  years. Hemoptysis was identified in 40% of patients with TBDM. Grade 3+ sputum smear positivity was observed in 12% in the TB group and 41.8% patients in the TBDM group. The study concluded that the presentations in patients of TB with T2DM and patients without T2DM are different.

Hariprasad S et al<sup>62</sup>, conducted a study in 100 diabetes mellitus patients with pulmonary tuberculosis. Anorexia, cough, fever were the predominant clinical symptoms identified with 80%, 73% and 56% respectively. Majority of the male patients were smokers with 62.5%. Around 10% of the patients were identified with clubbing. Anemia and erythrocyte sedimentation rate above 50mm/hr were identified with 51% and 52% respectively. The average duration of diabetes and the average FBS value was 6.6 years and 234.4 mg/dl, respectively. Sputum positive for acid-fast bacilli under the age of 40 years were identified in 81% of the patients.

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Cavitary lesions, infiltration and fibrosis were identified with 53%, 38% and 37% respectively. Lung field involvement was identified in 32% of the cases. The study concluded that diabetes has no effect on the presenting features of pulmonary tuberculosis.

Anusuya M. et al<sup>40</sup>, performed a cross-sectional study in 100 patients. The purpose of the study was to determine the pattern, presentation of tuberculosis and the factors influencing the prevalence among TB patients with diabetic mellitus. Majority of the patients were males, with 70% followed by females with 30%. Majority of the patients were under the age group of more than 40 years, with 78%. Anorexia, cough and loss of weight were the major clinical presentation with 82%, 77% and 44% respectively. Past history of TB and family history of TB were identified with 20% and 15% respectively. The mean duration of diabetes in TB patients was 6.8 years. Anemia was identified in 55% of cases. The mean FBS value and mean PPBS value were observed with 236.4 mg/dl and 351.5 mg/dl, respectively. ESR >50 mm/hr was identified in 57% of the patients. Sputum positivity in an age of less than 40 years and in age more than 40 years were 86% and 54% respectively. Lower lobe involvement, predominant right-side involvement, left side involvement, and bilateral involvement was observed with 34%, 39%, 30% and 31% respectively. Cavitation was the most frequent lung change observed in both less than and more 40 years age group with 55%. Whereas, fibrosis and infiltration were the second frequent pattern in age more than 40. The study concluded the association between TB and DM.

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Roghieh G et al<sup>63</sup>, conducted a retrospective cross-sectional study in 200 patients. The purpose of the study was to determine the effect of Diabetes Mellitus on clinical, diagnostic and radiological features of pulmonary TB. Data between the groups were compared using the SPSS-16, Fischer's exact test and chi-square test. TB and concurrent DM were identified in 40% of the patients. Females were identified with more coincidental TB and DM. Fever, dyspnea, weight loss and hemoptysis showed a significant difference between the groups. The most frequent diagnostic method in both groups was the positive sputum smear. Diabetic patients are identified more with multilobar cavities. The study concluded that diabetic patients are observed with more invasive TB.

Kouismi H et al<sup>64</sup>, performed a retrospective study in 80 patients. The objective of the study was to determine the characteristics of pulmonary tuberculosis in patients with diabetes. The study results revealed that older patients with tuberculosis and the male patients were more prone to develop diabetes. Type 2 diabetes was identified in 63.3% of the patients. Patients with diabetes are identified with more involvement of basal segments of the lower lobes and cavitation. The time for conversion to negative of sputum culture in control and case-patients were  $44.1 \pm 20.2$  days and  $36 \pm 18.3$ . The study concluded the association between TB and DM.

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Mukarram Siddiqui A. et al<sup>65</sup>, conducted a study in 216 tuberculosis patients. The purpose of the study was to compare the clinical manifestations and outcome of tuberculosis between diabetic and non-diabetic patients. Diabetes was identified in 16% of the participants. The most common site affected was pulmonary tuberculosis. Pulmonary tuberculosis was associated with poor glycemic control. Smear positivity for acid-fast bacilli was similar in both the groups. The study concluded that pulmonary tuberculosis is common in patients with diabetics.

Shital P et al<sup>66</sup>, conducted a prospective study in 200 patients. The purpose of the study was to identify the clinical-radiological overlap and delayed sputum conversion in TB patients with DM. The prevalence of pulmonary tuberculosis with DM and without DM were 70.5% and 86.5% respectively. Whereas EPTB with DM and without DM were observed with 29.5% and 13.5% respectively. Lower Lung fields involvement with DM and without DM were identified with 24.11% and 6.35%. The presence of pulmonary Cavities DM and non-DM patients with 39% and 28.32% respectively was reported. Sputum conversion at intensive phase completion was observed in “cases of PTB” with and without DM with 76.53% & 92.70% respectively. The study concluded that the presence of DM can affects “the clinical, bacteriological and radiological presentation of PTB”.



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Olayinka AO et al<sup>67</sup>, conducted a cross-sectional study of 351 patients with TB. The purpose of the study was to identify the co-existence of DM and TB in persons with established TB. The study results revealed that 5.7% was the prevalence of DM in patients with TB. Diabetes mellitus was diagnosed at the screening in 2.8% of the participants. The mean age of the participants and the mean duration of TB symptoms were  $34.9 \pm 13.21$  years and  $9.65 \pm 9.49$  months. The most predominant symptom was weight loss, with 94%. The study concluded the need for the screening for DM in persons with TB

Magee MJ et al<sup>68</sup>, performed a study in 1671 adult TB patients. The aim of the study was to evaluate the characteristics of TB in patients with and without diabetes. Diabetes was identified in 11.1% of the patients. The prevalence of multidrug-resistant TB in patients without and with previous TB treatment was 23% and 26% respectively. Among 149 TB–DM patients with DST results, drug-susceptible TB and drug-resistant TB were identified with 69.8% and 30.2% respectively. Favorable TB outcome was identified in 78.7% of the TB–DM patients. The study concluded that diabetes is common in TB patients at high risk for drug-resistant TB.

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Munna NH et al<sup>69</sup>, performed a cross-sectional study in 125 patients. The purpose of the study was to identify the rate and effect of Diabetes mellitus in patients with Pulmonary Tuberculosis. The study results revealed that 26.4% was the prevalence of DM in pulmonary TB patients, while 20.8% in non-diabetic patients. The relative risk of DM 1.27 times higher in the TB patients as compared to non-TB person. Hemoptysis was more common in diabetic patients, with 45% as compared to non-diabetic patients with 13%. Whereas, fever is more common in non-diabetic patients, with 88% as compared to diabetic patients with 57%. Among diabetic pulmonary TB patients, the sputum positivity was more common with 69%. Chest X-ray in pulmonary TB patient with DM showed a cavitory lesion with 33% and 9.76% in the non-diabetic patients. This study concluded that the prevalence of DM in pulmonary TB patients is higher compared to non-pulmonary TB patients.

Siddiqui AM. et al<sup>70</sup>, performed a study in 64 patients. The purpose of the study was to compare the radiological manifestations of tuberculosis between diabetics and non-diabetics. Upper lobe involvement, lower lobe, Bilateral involvement and cavities were identified in diabetic patients with 81%, 72%, 53% and 68% whereas in non-diabetics with 88%, 53%, 56% and 54% respectively. Through the present study, it was concluded that the radiological presentations of tuberculosis in the diabetics and non-diabetics were similar.

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Wu H et al<sup>71</sup>, performed a study in 71 patients. The aim of the study was to identify the changes in pulmonary tuberculosis in diabetic and non-diabetic patients before and after anti-tuberculosis therapy. The study results revealed a higher detection rate of lesions at the lower lung lobe, non -segmental consolidation and singular or multiple cavities within the lesion in TB patients with diabetes with 30%, 26.7% and 50% respectively. The detection rate of consolidation, nodules, bud-in-tree sign, singular and multiple cavities and pleural effusion after the 6-month anti-tuberculosis therapy showed statistical significance. The study concluded that the information required for the diagnosis and management of TB in diabetic and non-diabetic patients can be provided by the CT scans.

Alavi SM et al<sup>6</sup>, conducted a study in 148 patients. The purpose of the study was to determine the impact of diabetes mellitus on the clinical and paraclinical aspects of pulmonary TB. The study results revealed that  $56.6 \pm 12.7$  and  $44.8 \pm 18.3$  were the mean age of TB with DM and TB without DM patients. Cough, night sweating, fever, and weight loss were statistically similar between the groups. Sputum, hemoptysis and dyspnea were identified in TB patients with DM with 69.4%, 44.5% and 20.5% whereas, in TB patients without DM with 33.4%, 36.6% and 9.8% respectively. In TB patients with DM, a chest x-ray revealed cavitation and reticulonodular pattern with 55.5% and 31.2%. The rate of sputum smear positivity in TB patients with DM was 66.6% while 47.3% in TB patients without DM. The clinical and paraclinical aspects of pulmonary TB with DM are concluded.

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Duangrithi D et al<sup>72</sup>, conducted a prospective study in 227 participants. The aim of the study was to determine the impact of diabetes mellitus on clinical parameters and treatment outcomes in patients with pulmonary tuberculosis. The study results revealed that 16.3% of the participants had diabetes mellitus. Among them, 70.3% had DM prior to PTB diagnosis, whereas, 29.7% had DM at PTB diagnosis. The mycobacterium burden, conversion rate of sputum- culture, multidrug- resistant tuberculosis, frequency of adverse drug events from anti- TB medications, treatment outcomes and relapse rate were similar between the groups. The anorexia and hemoptysis were more common in PTB patients with DM while cough was more common in PTB patients without DM. This study concluded that all the newly diagnosed PTB patients should be monitored for the plasma glucose levels.

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# MATERIALS & METHODS



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## MATERIALS AND METHODS:

**Study site:** This study was conducted in the department of General Medicine at R.L.JALAPPA hospital, Kolar.

**Study population:** All the Pulmonary tuberculosis patient, with or without diabetes aged more than 18 years in the department of General Medicine at R.L.JALAPPA hospital, Kolar were considered as the study population.

**Study design:** The current study was a prospective observational study

**Sample size:** Sample size was calculated assuming the proportion of diabetes mellitus with TB as 29.03% as per the study by Soundararajan Raghuraman et al<sup>39</sup>, The other parameters considered for sample size calculation were 7% absolute precision and 95% confidence level. The following formula was used for sample size as per the study.

$$N = \frac{Z^2 P(1 - P)}{d^2}$$

Where  $n$  = Sample size

$Z$  = Z statistic for a level of confidence level = 1.960

$P$  = Expected prevalence/proportion of outcome = 0.2903

$d$  = Precision = 0.07

The required sample size as per the above-mentioned calculation was 162. To account for a non-participation rate of about 1%, another 1 subject will be added to the sample size. Hence the final required sample size would be 163.

**Sampling method:** All the eligible subjects were recruited into the study consecutively by convenient sampling till the sample size is reached.

**Study duration:** The data collection for the study was done in between January 2019 to July 2020.

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**Inclusion Criteria:**

1. Pulmonary tuberculosis patient, with or without diabetes aged more than 18 years.

**Exclusion criteria:**

1. Tuberculosis patients with HIV co-infection.
2. “Patients receiving chemotherapeutic drugs, radiotherapy and immunosuppressive therapy were also excluded”.
3. Chronic kidney disease.
4. Other pulmonary parenchymal diseases should be excluded

**Ethical considerations:** Study was approved by the institutional human ethics committee. Informed written consent was obtained from all the study participants, and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and the voluntary nature of participation were explained to the participants before obtaining consent. Confidentiality of the study participants was maintained.

**Data collection tools:** All the relevant parameters were documented in a structured study proforma.

**Methodology:**

This was a duration-based study from January 2018 to June 2019. Patients of pulmonary tuberculosis at ending the outpatient care and Inpatient care of the department of internal medicine and pulmonary medicine, fulfilling the inclusion and exclusion criteria were included in the study. Informed written consent was taken from all subjects. A pre-structured case record form was used to collect the data. A detailed history and thorough clinical examination were done.

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Pulmonary tuberculosis was diagnosed by detailed history, clinical examination, sputum examination for acid-fast bacilli, chest radiography and CB- NAAT. Diabetes mellitus was diagnosed using the national diabetes data group and WHO diagnostic criteria:

1. Symptom of diabetes plus “random blood sugar > 11.1 mmol/L” (200 mg/dl) or
2. “Fasting plasma glucose > 7.0 mmol/L (126 mg/dl)” or
3. “Two-hour plasma glucose > 11.1 mmol/L (200 mg/dl) “during and oral glucose tolerance test.

**Investigations:**

- Complete hemogram
- Chest x-ray
- HbA1C
- Erythrocyte sedimentation rate
- Fasting blood sugar
- Postprandial blood sugar
- Sputum AFB
- Total leukocyte count
- CB- NAAT

**Statistical Methods:**

- Hemoglobin, Neutrophils, Total Count, Lymphocytes, Fasting Blood Sugar, Post Prandial Blood Sugar, Hba1c, Side of the lesion, lung fields and radiological appearance were considered as primary outcome variables.
- Age, gender, past history, presenting complaints, general physical examinations, vital sign examinations, respiratory system examinations were considered to study relevant variables.



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- Study Group (Diabetic v/s Non-Diabetic) was considered as an explanatory variable.
  - All Quantitative variables were checked for normal distribution within each category of an explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro-wilk test was also conducted to assess normal distribution. Shapiro-wilk test p value of  $>0.05$  was considered as a normal distribution.
  - The association between categorical explanatory variables and the quantitative outcome was assessed by comparing the mean values. Independent sample t-test was used to assess the statistical significance of normally distributed variables, and the Mann Whitney U test was used to assess the statistical significance of non-normally distributed variables.
  - The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Odds ratio, along with 95% CI, is presented. Chi square test was used to test statistical significance.
  - P value  $< 0.05$  was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.<sup>73</sup>

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# RESULTS



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## RESULTS:

A total of 163 subjects were included in the final analysis, with 79 participants were diabetic, and 84 participants were non-diabetic.

**Table 4: Comparison of age between the study group (n=163)**

Parameter	Study group (Mean± SD)		P value
	Diabetic (n=79)	Non-Diabetic (n=84)	
Age	55.76 ± 12.6	44.27 ± 18.04	<0.001

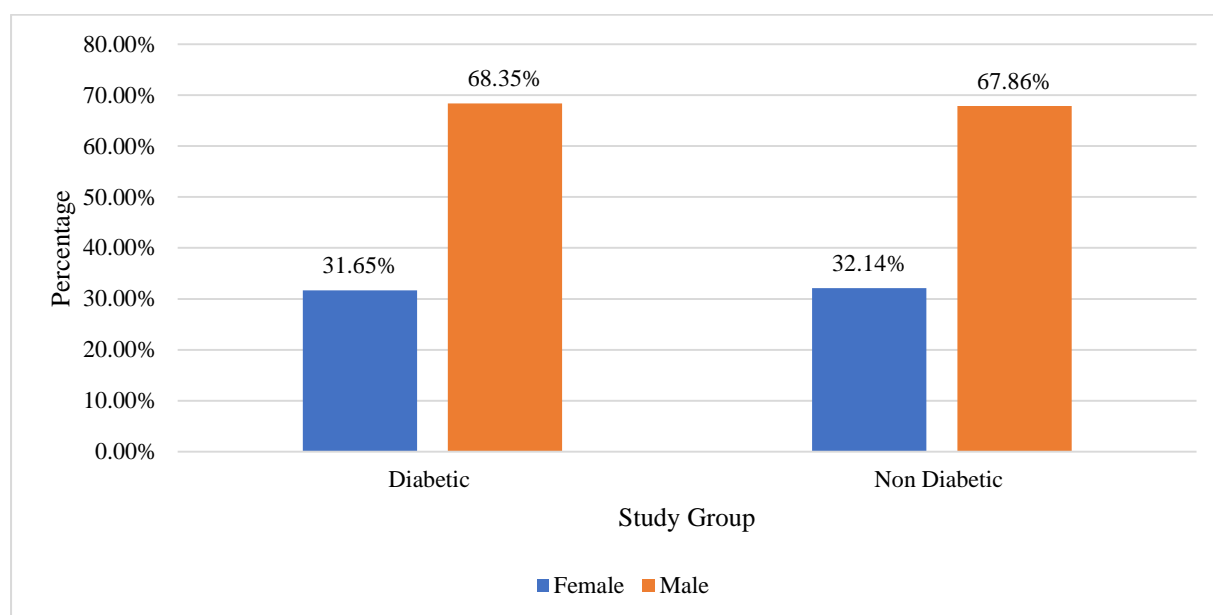
The mean age in diabetics was 55.76 ± 12.6 years, and in non-diabetics, the mean age was 44.27 ± 18.04 years. The mean difference in age between the study group was statistically significant. (P Value<0.05). (Table 4)

**Table 5: Comparison of gender between the study group (n=163)**

Gender	Study Group		Chi square	P value
	Diabetic (n=79)	Non-Diabetic (n=84)		
Female	25 (31.65%)	27 (32.14%)	0.005	0.946
Male	54 (68.35%)	57 (67.86%)		

Out of 79 participants in diabetics, 25 (31.65%) participants were female, and 54 (68.35%) participants were male. Out of 84 participants in non-diabetics, 27 (32.14%) participants were female, and 57 (67.86%) participants were male. The difference in the proportion of gender between the study group was not statistically significant. (P Value>0.05). (Table 5 & Figure 2)

**Figure 2: Clustered bar chart for comparison of gender between the study group (n=163)**

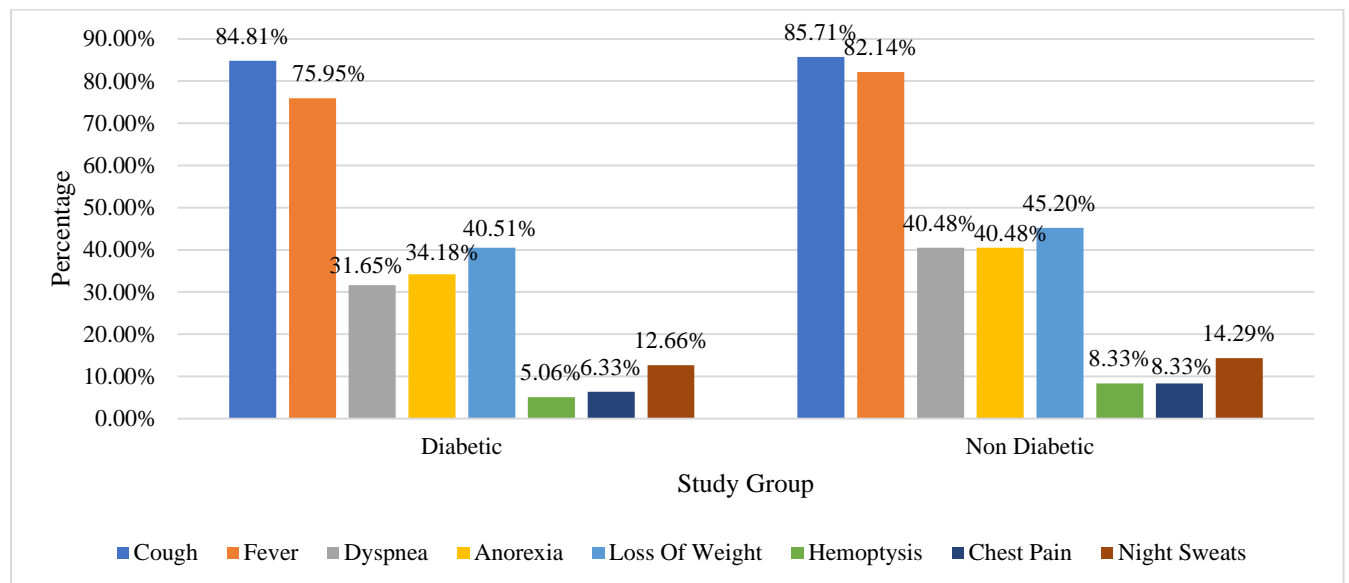


**Table 6: Comparison of presenting complaints between the study group (n=163)**

Presenting Complaints	Study Group		Chi square	P value
	Diabetic (n=79)	Non-Diabetic (n=84)		
Cough	67 (84.81%)	72 (85.71%)	0.027	0.871
Fever	60 (75.95%)	69 (82.14%)	0.946	0.331
Dyspnea	25 (31.65%)	34 (40.48%)	1.375	0.241
Anorexia	27 (34.18%)	34 (40.48%)	0.690	0.406
Loss Of Weight	32 (40.51%)	38 (45.2%)	0.372	0.542
Hemoptysis	4 (5.06%)	7 (8.33%)	0.692	0.406
Chest Pain	5 (6.33%)	7 (8.3%)	0.240	0.624
Night Sweats	10 (12.66%)	12 (14.29%)	0.092	0.761

Out of 79 participants in diabetics, 67 (84.81%) participants had a cough, 60 (75.95%) participants had fever, 25 (31.65%) participants had dyspnea, 27 (34.18%) participants had anorexia, 32 (40.51%) participants had a loss of weight, 4 (5.06%) participants had hemoptysis, 5 (6.33%) participants had chest pain and 10 (12.66%) participants had night sweats. Out of 84 participants in non-diabetics, 72 (85.71%) participants had a cough, 69 (82.14%) participants had fever, 34 (40.48%) participants had dyspnea, 34 (40.48%) participants had anorexia, 38 (45.2%) participants had a loss of weight, 7 (8.33%) participants had hemoptysis, 7 (8.33%) participants had chest pain and 12 (14.29%) participants had night sweats. The difference in the proportion of all the presenting complaints between study groups was not statistically significant (P Value>0.05). (Table 6 & Figure 3)

**Figure 3: Clustered bar chart for comparison of presenting complaints between the study group (n=163)**

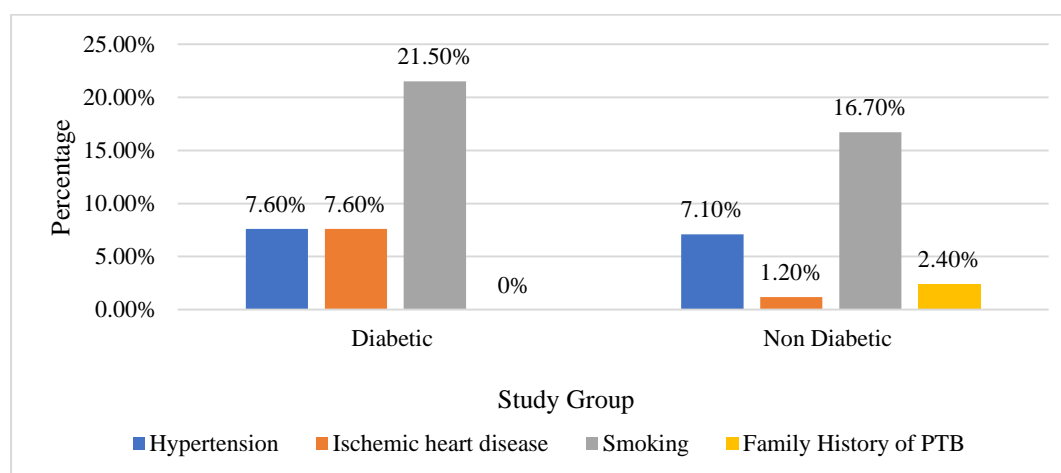


**Table 7: Comparison of past history between the study group (n=163)**

Past history	Study Group		Chi square	P value
	Diabetic (n=79)	Non-Diabetic (n=84)		
Hypertension	6 (7.6%)	6 (7.1%)	0.012	0.912
Ischemic heart disease	6 (7.6%)	1 (1.2%)	4.063	0.058
Smoking	17 (21.5%)	14 (16.7%)	0.622	0.430
Family History of PTB	0 (0%)	2 (2.4%)	*	*

*\*No statistical tests were applied due to 0-subjects in one of the cells.*

Out of 79 participants in the diabetic group, 6 (7.6%) participants had hypertension as past history, 6 (7.6%) participants had Ischemic heart disease as past history, 17 (21.5%) participants had smoking as past history, and no participant had a family history of PTB as past history. Out of 84 participants in the non-diabetic group, 6 (7.1%) participants had hypertension as past history, 1 (1.2%) participant had Ischemic heart disease as past history, 14 (16.7%) participants had smoking as past history, and 2 (2.4%) participants had a family history of PTB as past history. The difference in the proportion of all the past history (hypertension, Ischemic heart disease and smoking) between study group was not statistically significant (P Value>0.05). (Table 7 & Figure 4)

**Figure 4: Clustered bar chart for comparison of past history between the study group (n=163)**

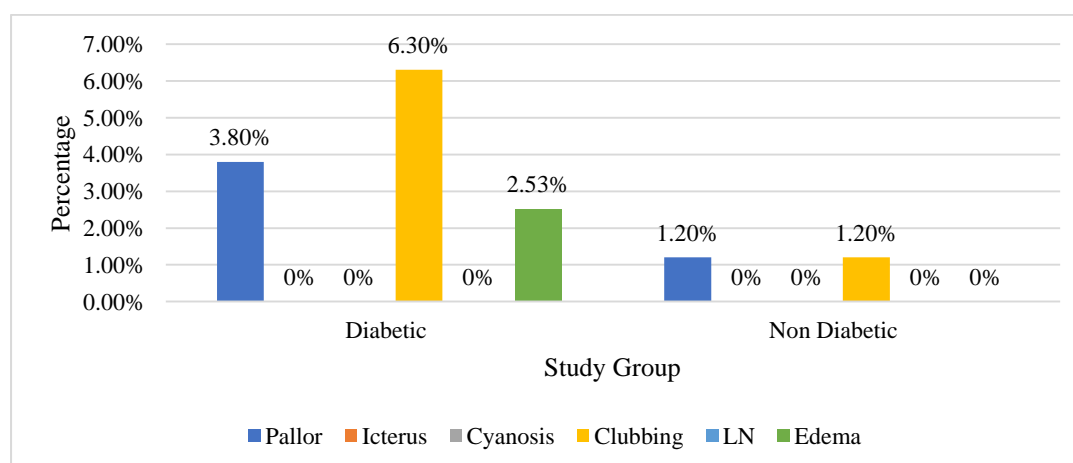
**Table 8: Comparison of general physical examinations between the study group (n=163)**

General physical examinations	Study Group		Chi square	P value
	Diabetic (n=79)	Non-Diabetic (n=84)		
Pallor	3 (3.8%)	1 (1.2%)	1.156	0.355 <sup>#</sup>
Icterus	0 (0%)	0 (0%)	*	*
Cyanosis	0 (0%)	0 (0%)	*	*
Clubbing	5 (6.3%)	1 (1.2%)	3.032	0.109 <sup>#</sup>
LN	0 (0%)	0 (0%)	*	*
Edema	2 (2.53%)	0 (0%)	*	*

<sup>#</sup> indicates fisher's exact test p value.

\*No statistical tests were applied due to 0-subjects in one of the cells.

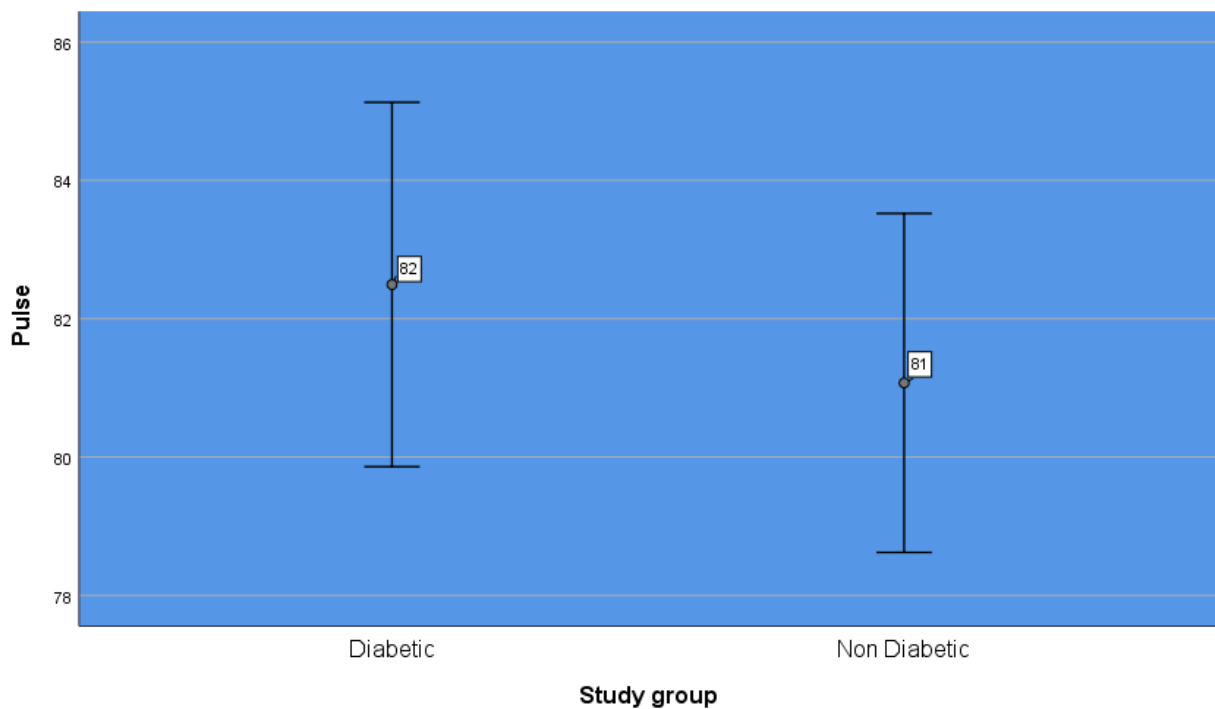
Out of 79 participants in diabetics, p for 3 (3.8%) participants, clubbing for 5 (6.3%) participants, and edema for 2 (2.53%) participants. Out of 84 participants in the non-diabetic group, the general physical examination was pallor for 1 (1.2%) participants and clubbing for 1 (1.2%) participants. None of the participants had Icterus, Cyanosis and LN as the general physical examination in diabetic as well as a non-diabetic group. The difference in the proportion of general physical examinations (pallor and clubbing) between study group was not statistically significant (P Value>0.05). (Table 8 & Figure 5)

**Figure 5: Clustered bar chart for comparison of general physical examinations between the study group (n=163)**

**Table 9: Comparison of vital signs examinations between the study group (n=163)**

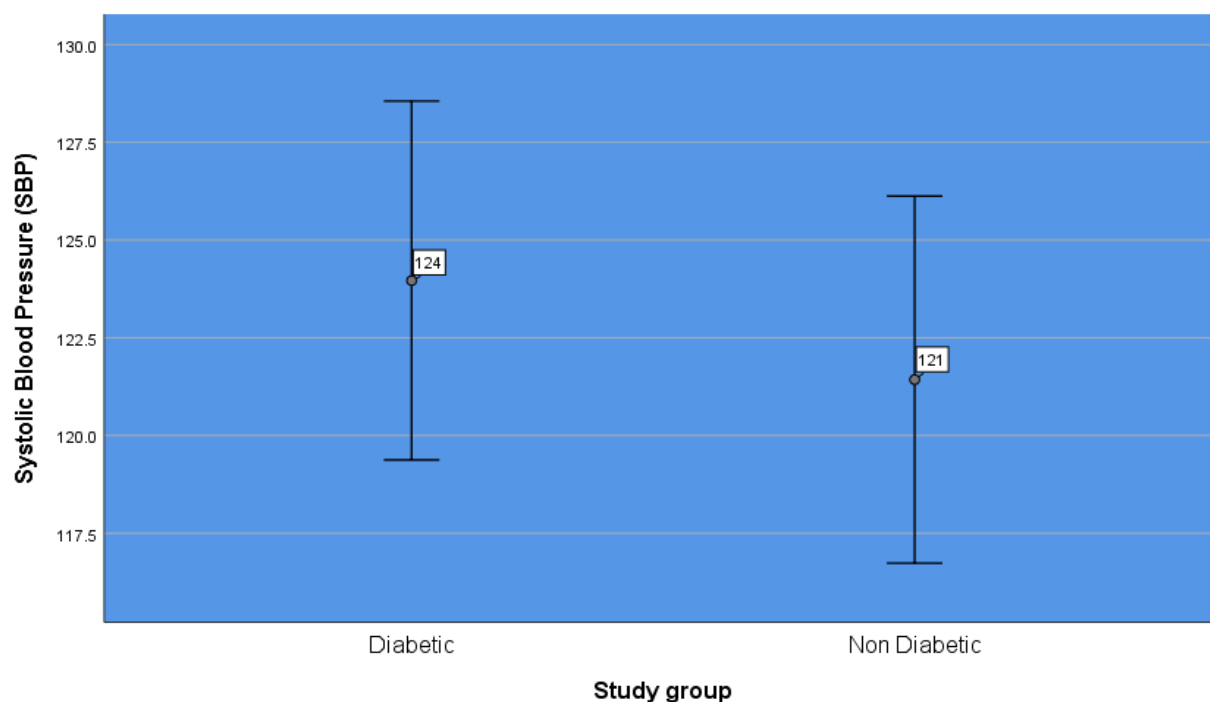
Parameter	Study group (Mean± SD)		P value
	Diabetic (n=79)	Non-Diabetic (n=84)	
Pulse (per min)	82.49 ± 11.76	81.07 ± 11.29	0.432
Systolic Blood Pressure (mm/hg)	123.96 ± 20.49	121.43 ± 21.63	0.444
Diastolic Blood Pressure (mm/hg)	78.61 ± 10.47	76.31 ± 11.49	0.185

The mean pulse was  $82.49 \pm 11.76$  per min. in the diabetic group, and it was  $81.07 \pm 11.29$  per min. in the non-diabetic group. The mean Systolic Blood Pressure was  $123.96 \pm 20.49$  mm/hg in the diabetic group, and it was  $121.43 \pm 21.63$  mm/hg in the non-diabetic group. The mean Diastolic Blood Pressure was  $78.61 \pm 10.47$  mm/hg in the diabetic group, and it was  $76.31 \pm 11.49$  mm/hg in the non-diabetic group. The mean difference in vital signs examination (Pulse, Systolic Blood Pressure and Diastolic Blood Pressure) was not statistically significant between the study group (P Value>0.05). (Table 9 & Figure 6,7,8)

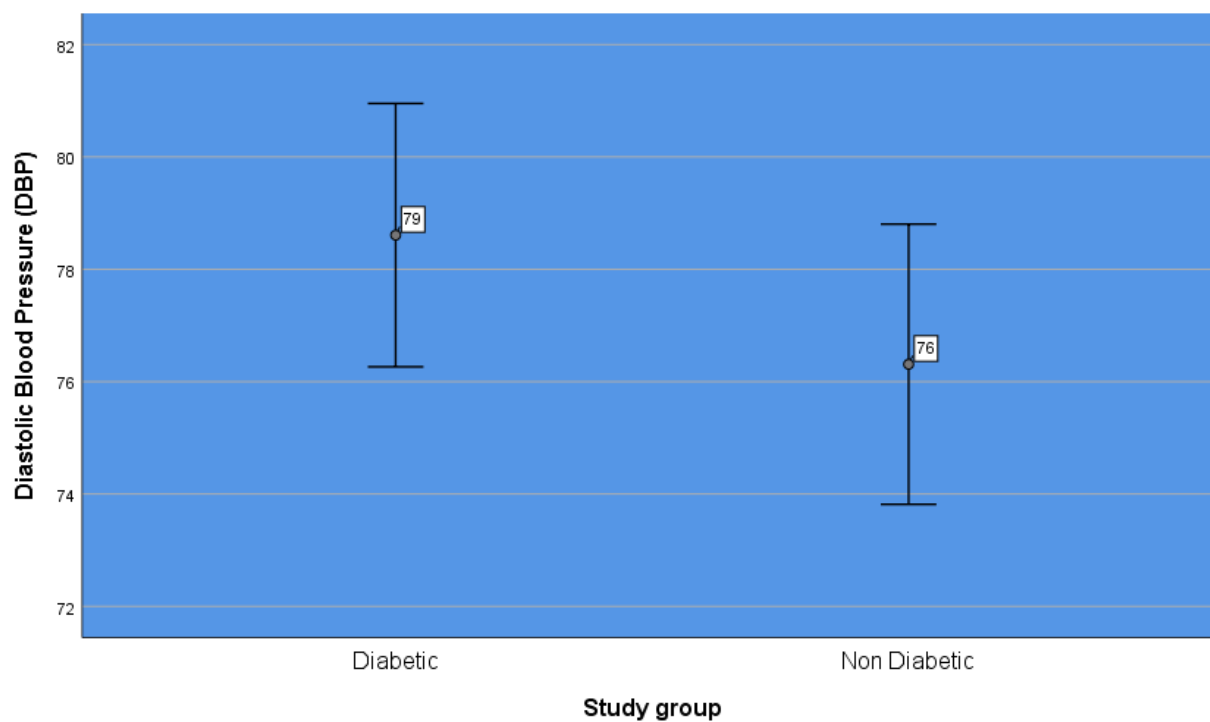
**Figure 6: Error bar chart for comparison of the pulse between the study group (n=163)**



**Figure 7: Error bar chart for comparison of systolic blood pressure between the study group (n=163)**



**Figure 8: Error bar chart for comparison of diastolic blood pressure between the study group (n=163)**

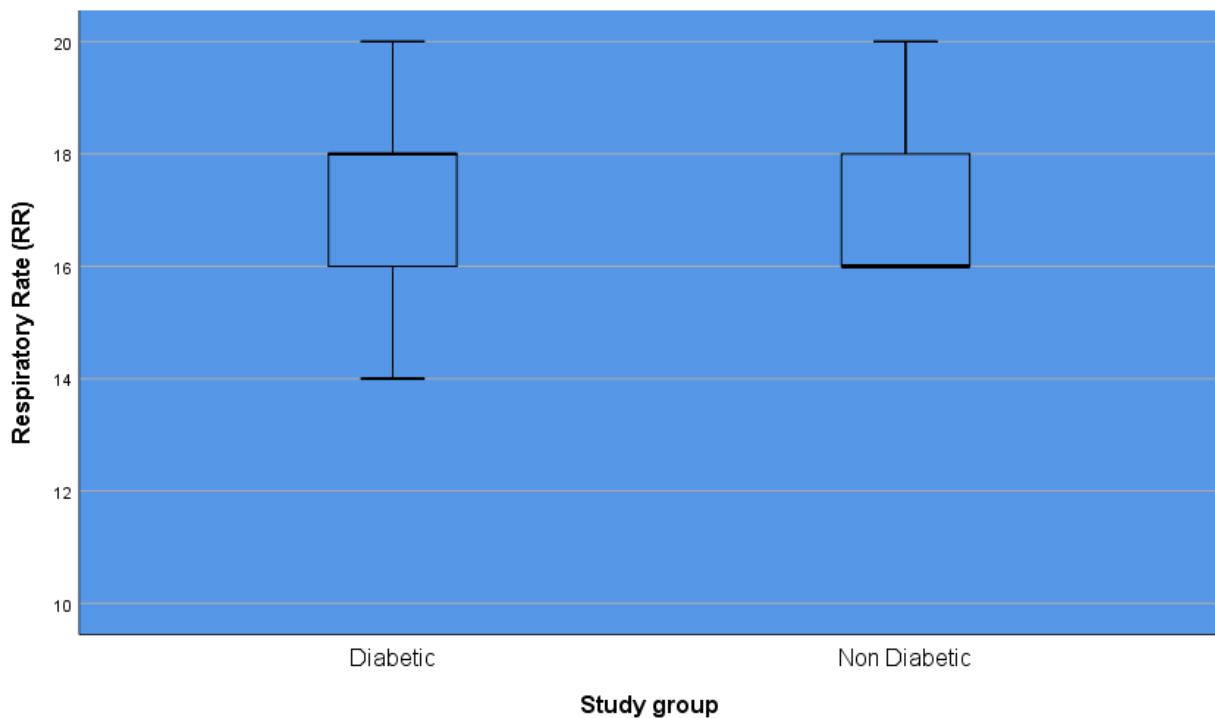


**Table 10: Comparison of respiratory rate between the study group (n=163)**

Parameter	Study group (Median (IQR))		Mann Whitney U test (P value)
	Diabetic (n=79)	Non-Diabetic (n=84)	
Respiratory Rate (cycles per min)	18.00 (16.00 to 18.00)	16.00 (16.00 to 18.00)	0.262

The median respiratory rate was 18.00 (16.00 to 18.00) cycles per minute in the diabetic group and 16.00 (16.00 to 18.00) cycles per minute in the non-diabetic group. The difference in median respiratory rate between study group was not statistically significant (P Value>0.05). (Table 10 & Figure 9)

**Figure 9: Box plot for comparison of respiratory rate between study group (n=163)**

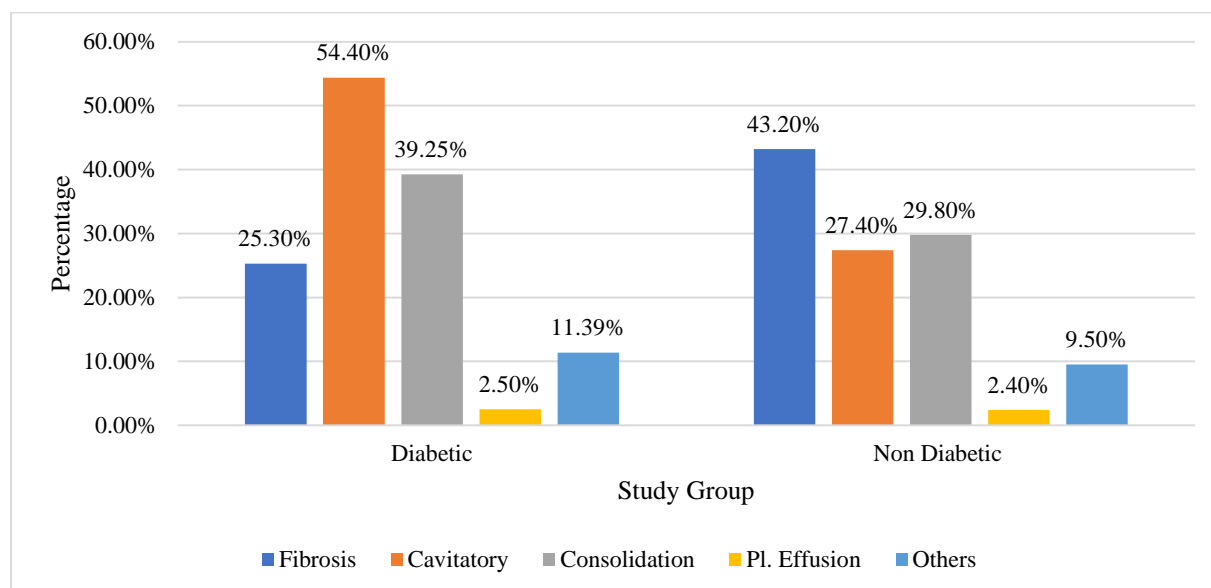


**Table 11: Comparison of respiratory system examinations between the study group (n=163)**

Respiratory system examinations	Study Group		Chi square	P value
	Diabetic (n=79)	Non-Diabetic (n=84)		
Fibrosis	20 (25.3%)	38 (43.2%)	7.049	0.008
Cavitary	43 (54.4%)	23 (27.4%)	12.362	<0.001
Consolidation	31 (39.24%)	25 (29.8%)	0.887	0.346
Pl. Effusion	2 (2.5%)	2 (2.4%)	0.004	0.950
Others	9 (11.39%)	8 (9.5%)	0.765	0.382

Out of 79 participants in the diabetic group, the respiratory system examination was Fibrosis for 20 (25.3%) participants, cavitary for 43 (54.4%) participants, Consolidation for 31 (39.24%) participants, Pl. Effusion for 2 (2.5%) participants and others for 9 (11.39%) participants. Out of 84 participants in the non-diabetic group, the respiratory system examination was Fibrosis for 38 (43.2%) participants, cavitary for 23 (27.4%) participants, Consolidation for 25 (29.8%) participants, Pl. Effusion for 2 (2.4%) participants and others for 8 (9.55%) participants. The difference in the proportion of Fibrosis and cavitary between the study group was statistically significant (P Value<0.05) while for Consolidation, Pl. Effusion and others, the difference in proportion was not statistically significant between study group (P Value>0.05). (Table 11 & Figure 10)

**Figure 10: Clustered bar chart for comparison of respiratory system examinations between the study group (n=163)**

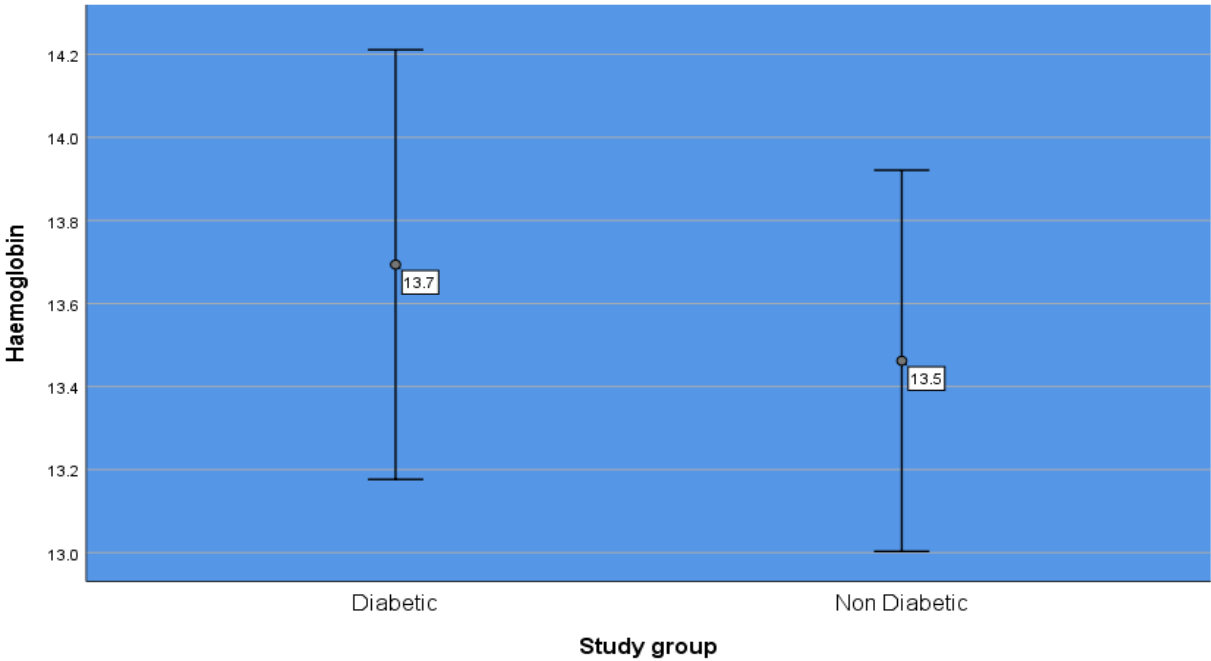


**Table 12: Comparison of various investigations between the study group (n=163)**

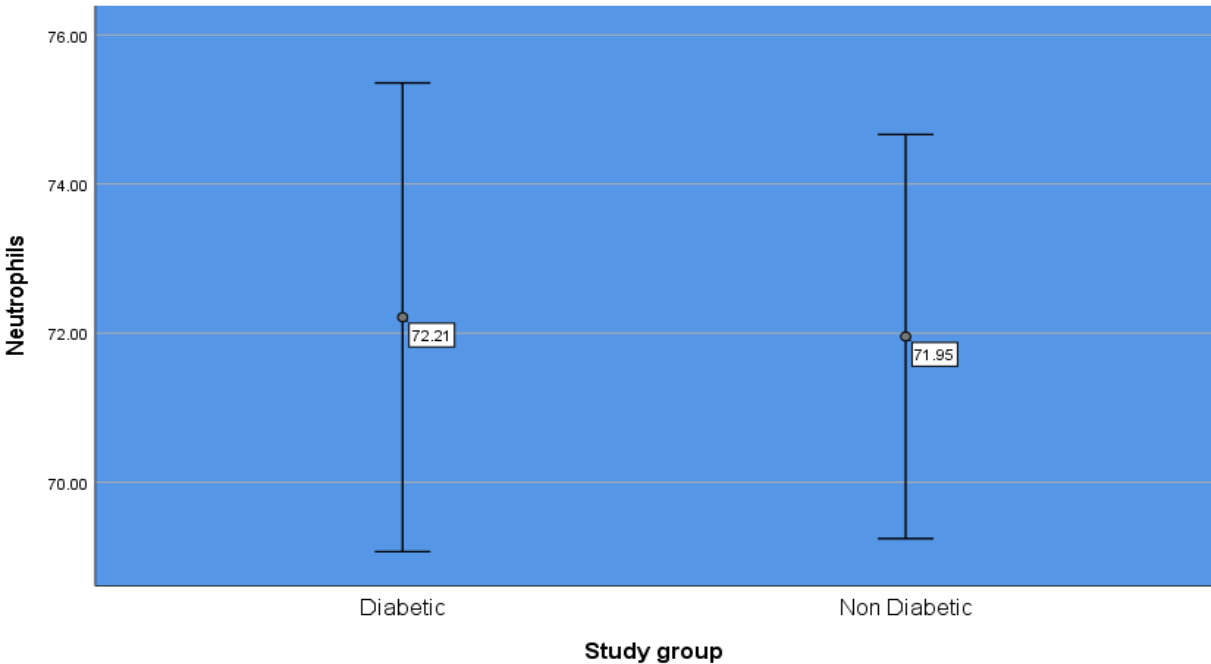
Parameter	Study group (Mean± SD)		P value
	Diabetic (n=79)	Non-Diabetic (n=84)	
Hemoglobin (g/dl)	13.69 ± 2.31	13.46 ± 2.12	0.505
Neutrophils	72.21 ± 14.03	71.95 ± 12.49	0.901

The mean Hemoglobin was  $13.69 \pm 2.31$  g/dl in the diabetic group, and it was  $13.46 \pm 2.12$  g/dl in the non-diabetic group. The mean Neutrophils was  $72.21 \pm 14.03$  in the diabetic group, and it was  $71.95 \pm 12.49$  in the non-diabetic group. The mean difference in Hemoglobin and Neutrophils was not statistically significant between the study group (P Value>0.05). (Table 12 & Figure 11, 12)

**Figure 11: Error bar chart for comparison of hemoglobin between study group (n=163)**



**Figure 12: Error bar chart for comparison of neutrophils between study group (n=163)**

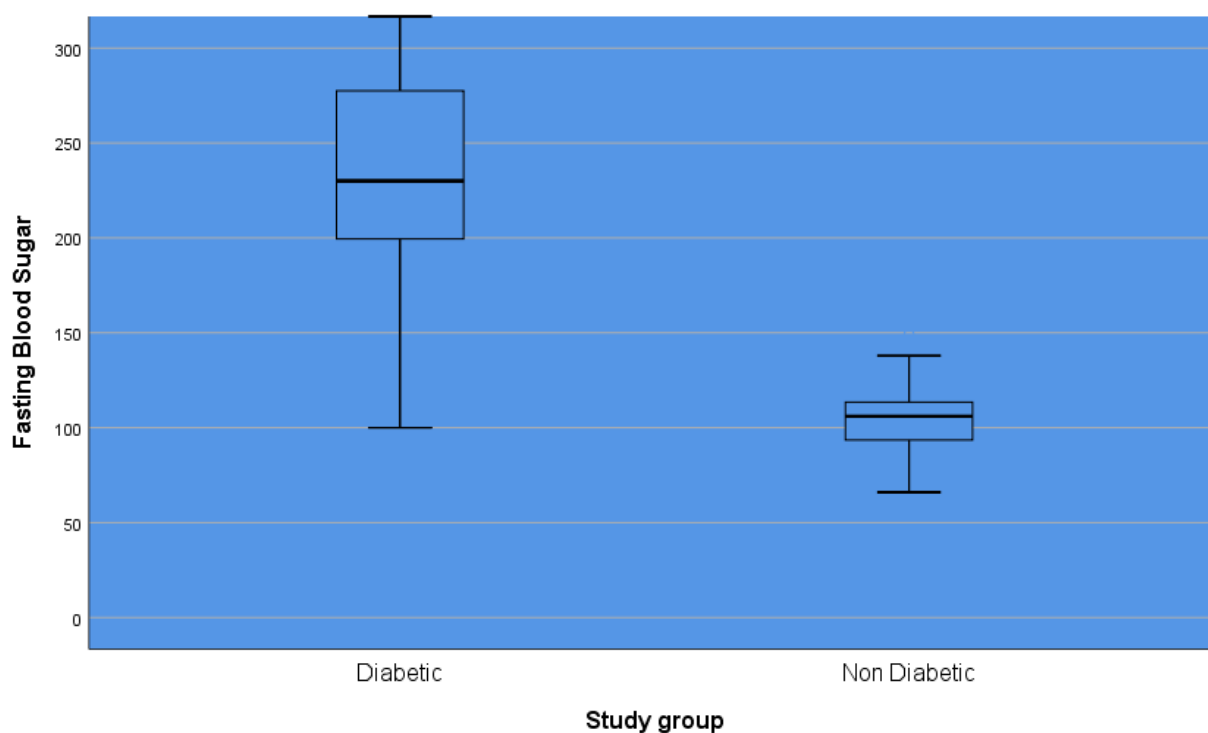


**Table 13: Comparison of various investigations between the study group (n=163)**

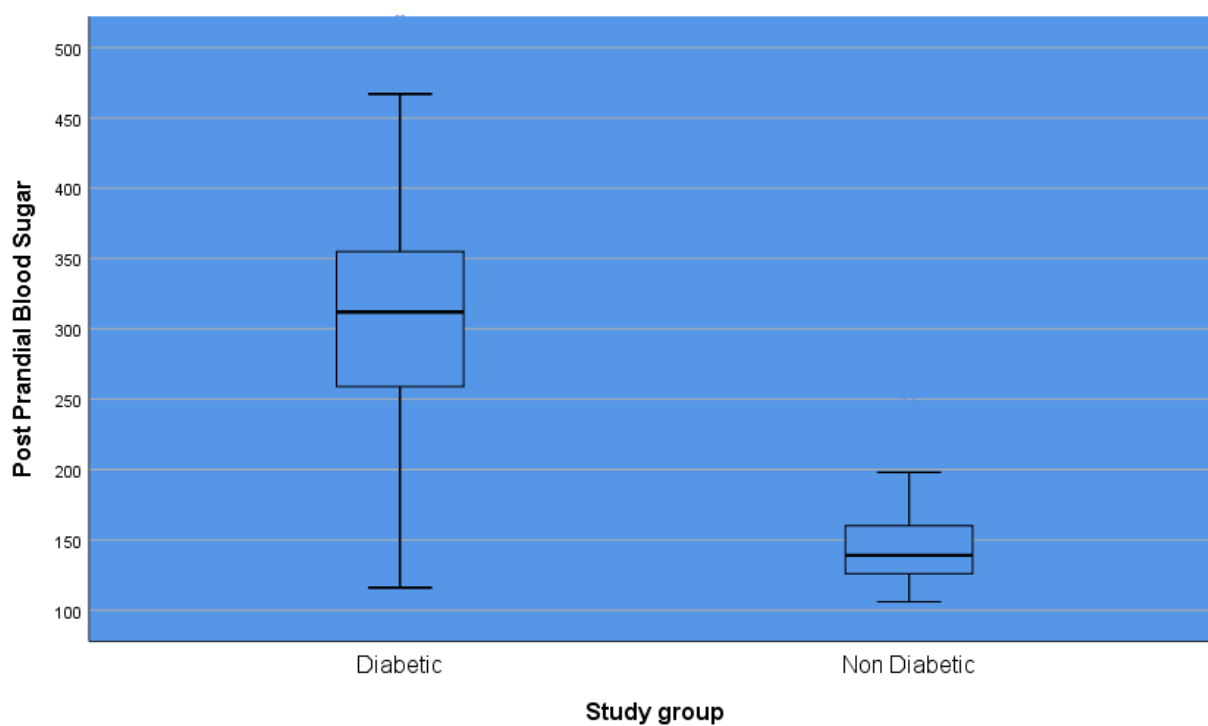
Parameter	Study group (Median (IQR))		Mann Whitney U test (P value)
	Diabetic (n=79)	Non-Diabetic (n=84)	
Total Count	9.0 (7.68 to 11.6)	9.0 (7.25 to 10.0)	0.443
Lymphocytes	34.5 (28.5 to 39.2)	36.0 (30.2 to 39.2)	0.583
Fasting Blood Sugar (mg/dl)	230 (199 to 278)	106.0 (93.3 to 113.8)	<0.001
Post Prandial Blood Sugar (mg/dl)	312 (256 to 355)	139.0 (126.0 to 160.0)	<0.001
HbA1c	9.7 (8.3 to 12.4)	5.4 (5.2 to 5.8)	<0.001

The median Total Count was 9.0 (7.68 to 11.6) in the diabetic group and 9.0 (7.25 to 10.0) in the non-diabetic group. The median Lymphocytes was 34.5 (28.5 to 39.2) in the diabetic group and 36.0 (30.2 to 39.2) in the non-diabetic group. The median Fasting Blood Sugar was 230 (199 to 278) mg/dl in diabetic group and 106.0 (93.3 to 113.8) mg/dl in the non-diabetic group. The median Post Prandial Blood Sugar was 312 (256 to 355) mg/dl in diabetic group and 139.0 (126.0 to 160.0) mg/dl in the non-diabetic group. The median HbA1c level was 9.7 (8.3 to 12.4) in the diabetic group and 5.4 (5.2 to 5.8) in the non-diabetic group. The difference in investigations of Total Count and Lymphocytes was not statistically significant between study group (P Value>0.05) while it was statistically significant for the investigations of Fasting Blood Sugar, Post Prandial Blood Sugar and HbA1c level (P Value<0.05). (Table 13 & Figure 13, 14, 115)

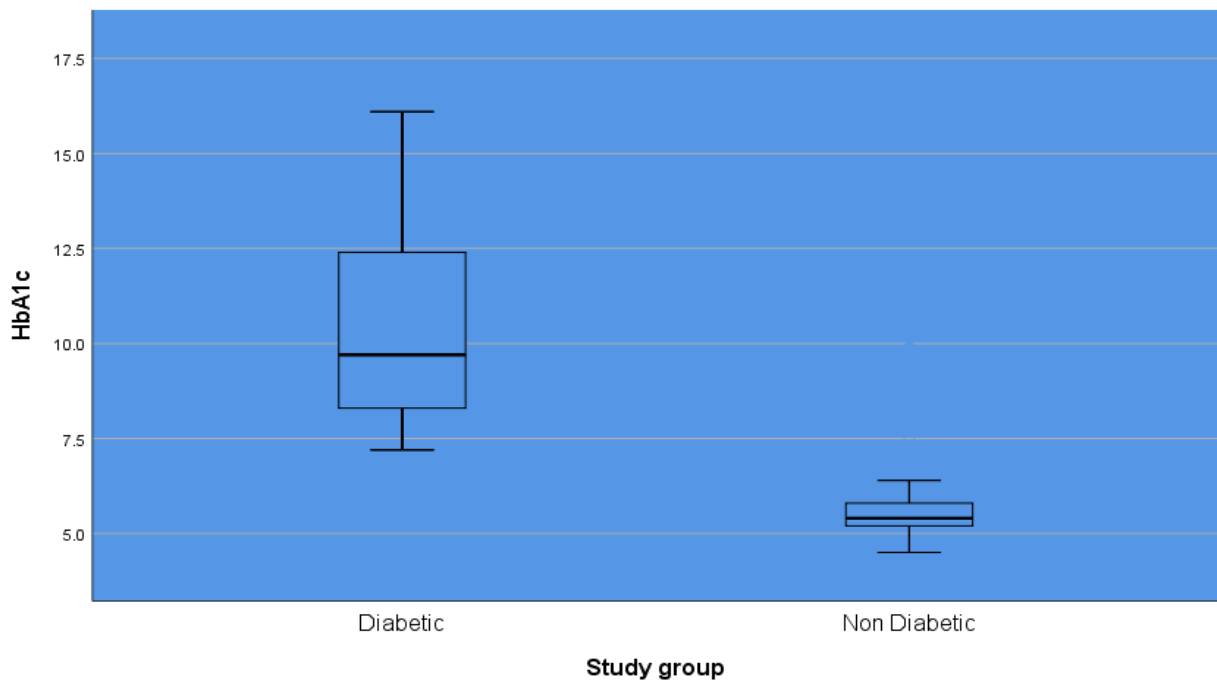
**Figure 13: Box plot for comparison of fasting blood sugar between study group (n=163)**



**Figure 14: Box plot for comparison of post prandial blood sugar between study group (n=163)**



**Figure 15: Box plot for comparison of Hba1c between study group (n=163)**



**Table 14: Comparison of chest x-ray between study group (n=163)**

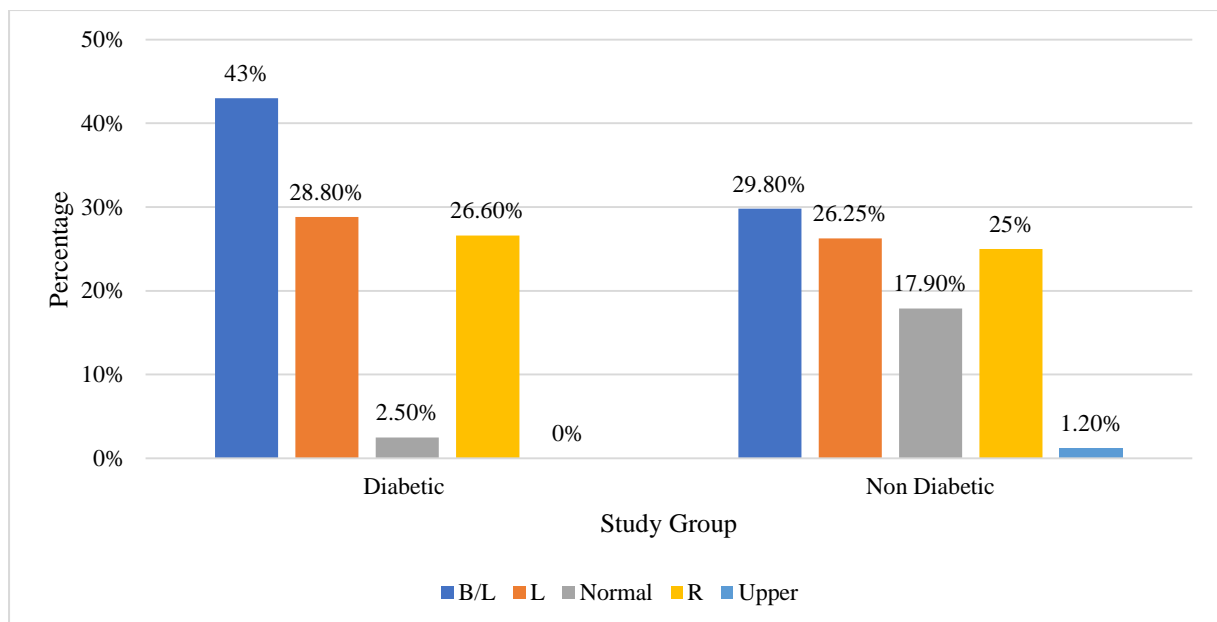
Chest x-ray	Study Group		Chi square	P value
	Diabetic (n=79)	Non-Diabetic (n=84)		
Side of Lesion				
Bilateral	34 (43.0%)	25 (29.8%)	*	*
Left	22 (28.8%)	22 (26.2%)		
Normal	2 (2.5%)	15 (17.9%)		
Right	21 (26.6%)	21 (25.0%)		
Upper	0 (0%)	1 (1.2%)		
Lung Fields				
lower	16 (20.3%)	11 (13.1%)	*	*
Middle	1 (1.3%)	3 (3.6%)		
Multilobar	35 (44.3%)	12 (14.3%)		
Normal	2 (2.5%)	15 (17.9%)		
P.ef	0 (0%)	1 (1.2%)		
Upper	25 (31.6%)	42 (50%)		

*\*No statistical test was applied due to 0-subjects in one of the cells.*

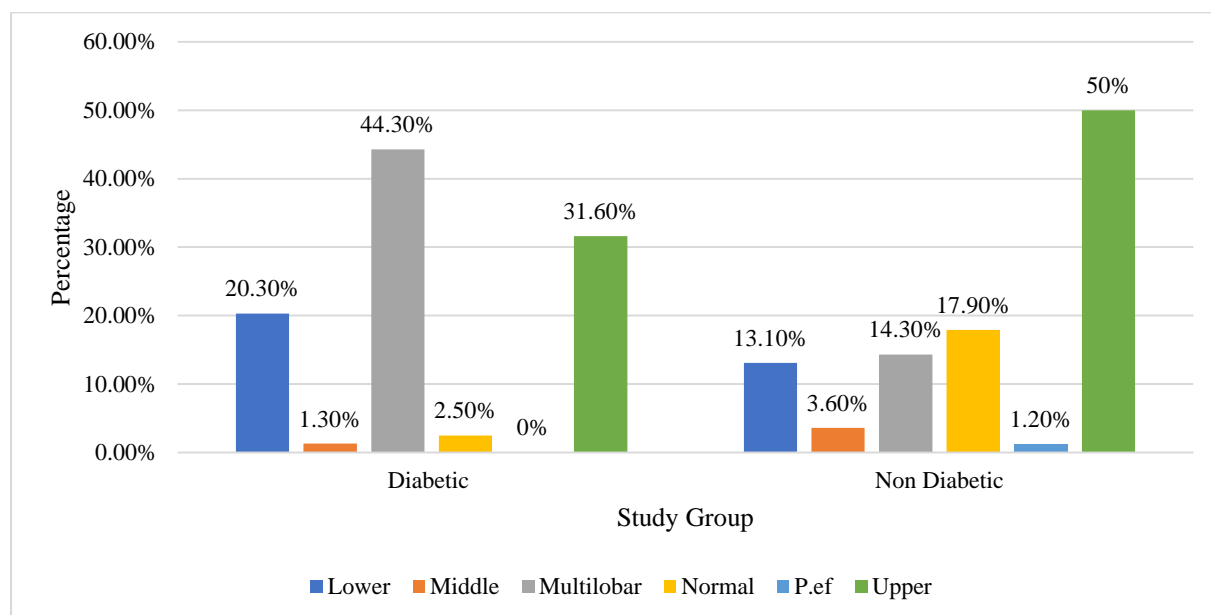


Out of 79 participants in diabetic group, the side of lesion was Bilateral for 34 (43.0%) participants, Left for 22 (28.8%) participants, Normal for 2 (2.5%) participants, Right for 21 (26.6%) participants and upper for no participant. Out of 84 participants in non-diabetic group, the side of lesion was Bilateral for 25 (29.8%) participants, Left for 22 (26.2%) participants, Normal for 15 (17.9%) participants, Right for 21 (25.0%) participants and upper for 1 (1.2%) participant. Out of 79 participants in diabetic group, the lung field was lower for 16 (20.3%) participants, Middle for 1 (1.3%) participant, Multilobar for 35 (44.3%) participants, Normal for 2 (2.5%) participants and upper for 25 (31.6%) participant. Out of 84 participants in non-diabetic group, the lung field was lower for 11 (13.1%) participants, Middle for 3 (3.6%) participant, Multilobar for 12 (14.3%) participants, Normal for 15 (17.9%) participants, P.ef for 1 (1.2%) participant and upper for 42 (50%) participants. (Table 14 & Figure 16, 17)

**Figure 16: Clustered bar chart for comparison of the side of the lesion between the study group (n=163)**



**Figure 17: Clustered bar chart for comparison of lung fields between the study group (n=163)**



**Table 15: Descriptive analysis of radiological appearance in the study population (n=163)**

Radiological appearance	Frequency	Percent (%)
Cavitary	24	14.7%
Consolidation	56	34.4%
Fibrocavitatory	19	11.7%
Fibrosis	30	18.4%
Normal	16	9.8%
Others	18	11.0%

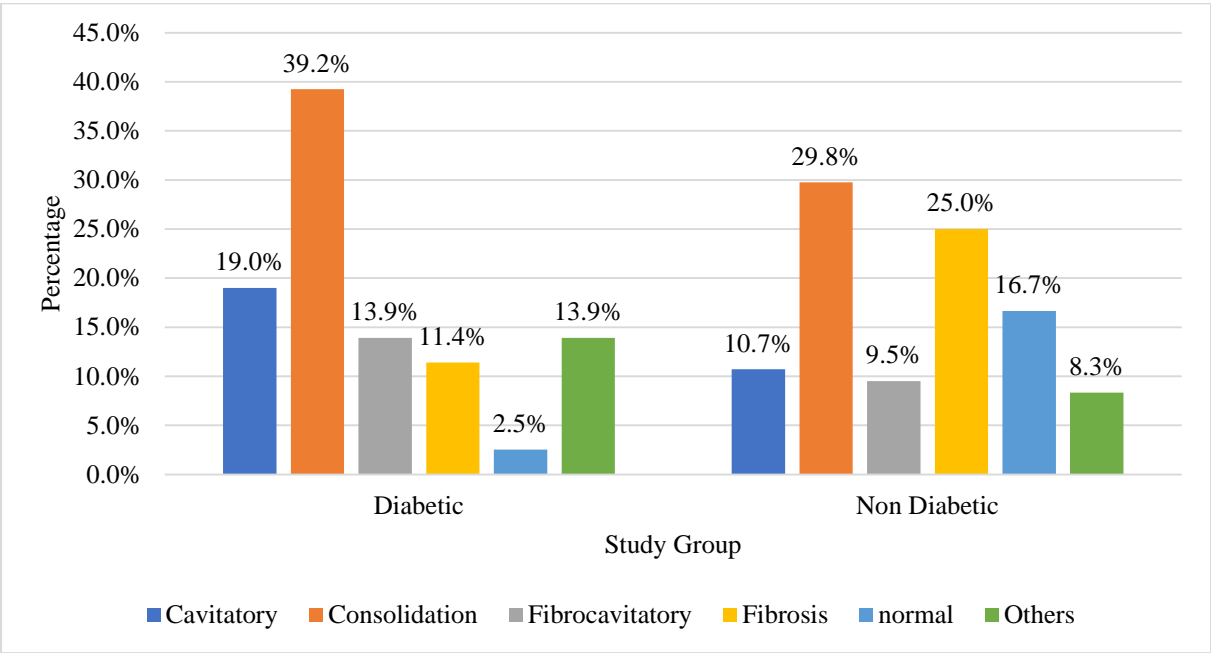
Among the study population, the radiological appearance was cavitary for 24 (14.7%) participants, Consolidation for 54 (34.4%) participants, Fibrocavitatory for 19 (11.7%) participants, Fibrosis for 30 (18.4%) participants, Normal for 16 (9.8%) participants and other for 18 (11.0%) participants. (Table 15)

**Table 16: Comparison of radiological appearance between the study group (n=163)**

Radiological Appearance	Study Group		Chi square	P value
	Diabetic (n=79)	Non-Diabetic (n=84)		
Cavitatory	15 (18.99%)	9 (10.71%)	17.168	0.004
Consolidation	31 (39.24%)	25 (29.76%)		
Fibrocavitatory	11 (13.92%)	8 (9.52%)		
Fibrosis	9 (11.39%)	21 (25%)		
Normal	2 (2.53%)	14 (16.67%)		
Others	11 (13.92%)	7 (8.33%)		

Out of 79 participants in diabetic group, the radiological appearance was Cavitatory for 15 (19%) participants, Consolidation for 31 (39.2%) participants, Fibrocavitatory for 11 (13.9%) participants, Fibrosis for 9 (11.4%) participants, Normal for 2 (2.5%) participants and others for 11 (13.9%) participants. Out of 84 participants in non-diabetic group, the radiological appearance was Cavitatory for 9 (10.7%) participants, Consolidation for 25 (29.8%) participants, Fibrocavitatory for 8 (9.5%) participants, Fibrosis for 21 (25%) participants, Normal for 14 (16.7%) participants and others for 7 (8.3%) participants. The difference in the proportion of radiological appearance between study group was statistically significant (P Value<0.05). (Table 16 & Figure 18)

**Figure 18: Clustered bar chart for comparison of radiological appearance between the study group (n=163)**



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# DISCUSSION



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## DISCUSSION:

Risk of tuberculosis infection is more in diabetic patients due to leukocyte dysfunction and reduction of serum bactericidal activity. Diabetic individuals have three times more risk for developing tuberculosis. The susceptibility of tuberculosis in diabetic patients is due to various factors like altered macrophage function, alteration in connective tissues due to glycosylation or due to reduced bronchial reactivity and dilatation. Diabetic individuals have three times more risk for developing tuberculosis. Clinical presentation and response to treatment both have a different course in diabetic individuals in comparison with non-diabetes individuals.<sup>55</sup>

Tuberculosis has been found to increase glucose intolerance and impact glycemic control in diabetes. Coexistence of diabetes and tuberculosis is more, and each affects other condition in a serious manner. Diabetes alters clinical features, radiological presentation, diagnosis, management and treatment outcomes of tuberculosis. Diabetes and tuberculosis are predominantly emerging as co-epidemic diseases. In India, the prevalence of tuberculosis is already more, and the prevalence of diabetes is increasing due to modern lifestyle changes. Active tuberculosis and reactivation of latent tuberculosis infections are more in diabetic patients leading to increased incidence of tuberculosis even after implementation of directly observed treatment for tuberculosis. Diabetes not only changes the clinical and radiological spectrum of tuberculosis but also leads to poor treatment adherence and outcomes. The main reason for poor adherence is the interaction of anti-diabetes drugs with antitubercular drugs leading to adverse reactions. When the differences in disease presentation, Sputum conversion and treatment outcomes in diabetes patients are understood better it will help in better management of both conditions.<sup>65</sup>

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This study aims to study the clinical spectrum of pulmonary tuberculosis in Diabetic and non-Diabetic patients, to study the radiographic spectrum of pulmonary tuberculosis in Diabetic and non-Diabetic patients, to study the difference in presentation among Diabetic and non-Diabetic patients.

Hemoglobin, Neutrophils, Total Count, Lymphocytes, Fasting Blood Sugar, Post Prandial Blood Sugar, HbA1c, Side of the lesion, lung fields and radiological appearance were considered as primary outcome variables. Age, gender, past history, presenting complaints, general physical examinations, vital sign examinations, respiratory system examinations were considered as study relevant variables. Study Group (Diabetic v/s Non-Diabetic) was considered as an explanatory variable. A total of 163 subjects were included in the final analysis, with 79 participants were diabetic, and 84 participants were non-diabetic. The mean age in diabetics was  $55.76 \pm 12.6$  years, and in non-diabetics, the mean age was  $44.27 \pm 18.04$  years. Out of 79 participants in diabetics, 31.65% of participants were female, and 68.35% of participants were male. Out of 84 participants in non-diabetics, 32.14% of participants were female, and 67.86% of participants were male. The mean age of diabetics is found to be higher than non-diabetics in the study participants. This finding is similar to that found in three similar studies, one by Alavi Syed Mohammed., et al<sup>6</sup>, other by Baghaei, P., et al<sup>74</sup>, and third by Ezung, T et al<sup>75</sup>, and can be attributed to two reasons. First is the incidence of diabetes increases with age, and second is the risk of developing TB infection or reactivation of latent infection also increases with age.

Out of 79 participants in diabetics, 84.81% participants had a cough, 75.95% participants had a fever, 31.65% participants had dyspnea, 34.18% participants had anorexia, 40.51% participants had a loss of weight, 5.06% participants had hemoptysis, 6.33% participants had chest pain, and 12.66% participants had night sweats.

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Out of 84 participants in non-diabetics, 85.71% participants had a cough, 82.14% participants had a fever, 40.48% participants had dyspnea, 40.48% participants had anorexia, 45.2% participants had a loss of weight, 8.33% participants had hemoptysis, 8.33% participants had chest pain, and 14.29% participants had night sweats. In the present study, the symptoms of cough, fever, dyspnea, anorexia, loss of weight, hemoptysis, chest pain and night seats are found to be more in non-diabetic patients than in diabetic patients which is contrary to the findings in similar studies where these symptoms and precisely dyspnea and hemoptysis where found to be more in diabetic patients than in non-diabetic patients. Studies by Baghaei, et al<sup>74</sup>, and Stevenson, C, R., et al<sup>2</sup>, demonstrated incidence of above mentioned symptoms more in diabetic patients than in non-diabetic patients.

Atypical radiographic pattern and distribution are observed for pulmonary tuberculosis in Patients of DM. Involvement of lower lobe of the lung was greater in “diabetic patients” with tuberculosis, whereas it is mainly upper lobe infiltration in non-diabetic patients. Out of 79 participants in the diabetic group, the respiratory system examination indicated fibrosis for 25.3% participants, Cavitary for 54.4% participants, Consolidation for 39.24% participants, Pl. Effusion for 2.5% participants and others for 11.39% participants. Out of 84 participants in the non-diabetic group, the respiratory system examination indicated fibrosis for 43.2% participants, Cavitary for 27.4% participants, Consolidation for 29.8% participants, Pl. Effusion for 2.4% participants and others for 9.55% participants. The cavitary radiological appearance was found to be more in diabetic patients when compared with non-diabetics. This is in confirmation with the finding that the risk of cavitation is increased in diabetic patients, particularly when there is poor glycemic control. Poor glycemic control reduces expression of The-related cytokines.



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This similar finding was found in a study by Baghaei, et al<sup>74</sup>, reported that diabetic patients had a higher prevalence of typical presentations along with cavitary lesions and in another study by Qazi, M, A., et al.<sup>76</sup> it was reported that Radiological signs of PTB are more pronounced in diabetics, 30 In patients with PTB alone, cavitation is less common with increasing age, while in diabetics of all ages, frequency of cavitation/LLF is high.

Out of 79 participants in the diabetic group, the affected lung field was lower for 20.3% participants, Middle for 1.3% participants, Multilobe for 44.3% participants, Normal for 2.5% participants and upper for 31.6% participant. Out of 84 participants in the non-diabetic group, the affected lung field was lower for 13.1% participants, Middle for 3.6% participants, Multilobe for 14.3% participants, Normal for 17.9% participants, P.ef for 1.2% participants and upper 50% participants. Diabetic patients usually have more severe features of tuberculosis like increased lung cavitation, increased involvement of lower lung fields and longer periods of smear positivity.<sup>66</sup> In the present study, lower lung involvement was more in diabetic patients, and upper lung infiltration was more in non-diabetic patients which is similar to that reported in several studies. In a study by Mohammed A shaikh., et al<sup>51</sup>, the PTB DM group of patients had increased frequency of lung lesions confined to lower lung field compared to PTB group. The PTB DM group of patients had a significantly higher frequency of cavitary lung lesions compared to PTB group. Also, cavitary lesions were more frequently confined to lower lung field in PTB DM group compared to PTB group. In another study by Siddiqui,<sup>70</sup> lower lobe involvement was found in 72% of diabetic patients against 53% of non-diabetic patients with tuberculosis and cavities were found in 68% of diabetic patients against 54% of non-diabetic patients.

In another study by Anasuya, M et al<sup>40</sup>, cavitation was observed more in diabetic patients with tuberculosis and in another study by Ikezoe, J et al<sup>77</sup>, it was observed that there was a high prevalence of nonsegmental distribution and multiple small cavities within any given lesion in lungs of diabetic patients with tuberculosis. Multilobar cavities were significantly more reported in diabetics in a study by Roghieh, G., et al.<sup>63</sup>

**Table 17: Radiological spectrum of lungs in diabetic patients**

<b>Study</b>	<b>Radiological spectrum of lungs in diabetic patients</b>
Present study	Lower lung lobe involvement and more cavitation.
Mohammed A shaikh., et al. <sup>78</sup>	PTB DM group of patients had a significantly higher frequency of cavitory lung lesions compared to PTB group.
Siddiqui, et al. <sup>65</sup>	lower lobe involvement was found in 72% of diabetic patients
Anasuya, M et al. <sup>40</sup>	More cavitation in lungs of diabetic patients.
Ikezoe, J et al. <sup>77</sup>	More cavitation in lungs of diabetic patients
Roghieh, G et al. <sup>63</sup>	More cavitation in lungs of diabetic patients

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## **CONCLUSION:**

This study found clinical presentation symptoms almost similar between diabetic patients with tuberculosis and non-diabetic patients with tuberculosis. The radiographic spectrum of tuberculosis was found to be different in diabetic patients. Diabetic patients were found to have more cavitation and involvement of lower lobe of lung as against upper lobe in non-diabetic patients. Hence the study concludes that radiographic assessment is best for diagnosis of tuberculosis in diabetic patients.

The following are the findings of the study:

- Increase in incidence of tuberculosis in diabetic patients increases with age.
- There is not much difference in the clinical presentation of tuberculosis in diabetic and non-diabetic patients.
- Radiographic presentation of tuberculosis differs among diabetic and non-diabetic patients.
- In diabetic patients with tuberculosis, there is increased cavitation in the lungs.
- In diabetic patients having tuberculosis, the lower lobe of the lung is more affected.

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## **LIMITATIONS:**

This study used only a small number of diabetic patients for the study, and all the patients are from a single hospital, and hence the results obtained cannot be generalized.

## **RECOMMENDATION:**

This study recommends increased education for diabetes patients about tuberculosis symptoms for better diagnosis and timely treatment.

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## **SUMMARY:**

Diabetes has been identified as an important risk factor for tuberculosis. Both diabetes and tuberculosis coexist, and each condition has its effect on the clinical and radiological spectrum of other condition. Diabetic patients are found to have more severe features of tuberculosis, and tuberculosis has been found to increase glucose intolerance and impact glycaemic control in diabetes. Diabetes alters clinical features, radiological presentation, diagnosis, management and treatment outcomes of tuberculosis. The risk of tuberculosis is two to five times greater in patients with diabetics as compared to non-diabetics. Many studies depict that pulmonary tuberculosis in a patient with type 2 diabetes mellitus have some different and specific presentations. The aim of the study was to determine the clinic - radiological spectrum of pulmonary tuberculosis in diabetics and non-diabetic patients. A total of 163 subjects were included in the final analysis, with 79 participants were diabetic, and 84 participants were non-diabetics. The radiographic spectrum of tuberculosis was found to be different in diabetic patients. Diabetic patients were found to have more cavitation and involvement of lower lobe of lung as against upper lobe in non-diabetic patients. Hence the study concludes that radiographic assessment is best for diagnosis of tuberculosis in diabetic patients.

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# ANNEXURES





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## STUDY PROFORMA

Name:

Date:

Sex:

Age:

O.P. / I.P. No:

Occupation:

### PRESENTING COMPLAINTS:

Cough:

Expectoration:

Fever

Night sweats:

Hemoptysis:

Chest pain:

Breathlessness:

Anorexia:

Loss of weight:

Others:

Past history:

Tuberculosis:

Diabetes:

Hypertension:

Ischemic heart disease:

Vitals-

PR-

BP-

RR-

TEMPERATURE-

### SYSTEMIC EXAMINATION-

CVS:

P/A:

CNS:

RS:

### INVESTIGATIONS:

HB

WBC

PLATELETS

DC

ESR

RBS

FBS

PPBS

HbA1C

SPUTUM AFB

SPUTUM C/S

CBNAAT

Chest x-ray findings:

CONCLUSION:

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**SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND  
RESEARCH, TAMAKA, KOLAR - 563101.**

**PATIENT INFORMATION SHEET**

This information is to help you understand the purpose of the study “**Clinico - Radiological Spectrum Of Pulmonary Tuberculosis In Diabetics And Non Diabetic Patients At Tertiary Care Centre**” You are invited to take part voluntarily in this research study, it is important that you read and understand the purpose, procedure, benefits and discomforts of the study.

What is the purpose of this study?

What are the various investigations being used? Are there any associated risks?

- Complete hemogram
- Chest x-ray
- HbA1C
- Erythrocyte sedimentation rate
- Fasting blood sugar
- Post prandial blood sugar
- Sputum AFB
- Total leukocyte count
- CB- NAAT

What is the benefit for me as a participant?

Participation in this research study may not change the final outcome . However, patients in the future may benefit as a result of knowledge gained from this study. You will not be charged extra for any of the procedures performed during the research study. Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at any time, without a penalty or loss of any benefits to which you were otherwise entitled before taking part in this study.

**CONFIDENTIALITY**

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available. Your original records may be reviewed by your doctor or ethics review board. For further information/ clarification please contact

DR. K. SREENATH REDDY, POST GRADUATE (M.D. GENERAL MEDICINE)  
DEPARTMENT OF GENERAL MEDICINE, SRI DEVRAJ URS MEDICAL COLLEGE,  
TAMAKA, KOLAR - 56310

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## **INFORMED CONSENT FORM**

**STUDY TITLE: CLINICO-RADIOLOGICAL SPECTRUM OF PULMONARY  
TUBERCULOSIS IN DIABETICS AND NON-DIABETIC PATIENTS AT TERTIARY  
CARE CENTRE**

**STUDY NUMBER:**

**SUBJECT'S NAME:**

**HOSPITAL NUMBER:**

**AGE:**

It is hoped that the knowledge of relevant prognostic factors might be useful for early identification of patients at high risk requiring intensive care treatment. If you agree to participate in the study we will collect information (as per proforma) from you or a person responsible for you or both. We will collect the treatment and relevant details from your hospital record. This information collected will be used for only dissertation and publication. The institutional ethical committee has reviewed this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

I understand that I remain free to withdraw from the study at any time and this will not change my future care. I have read or have been read to me and understood the purpose of the study, the procedure that will be used, the risk and benefits associated with my involvement in the study and the nature of information that will be collected and disclosed during the study. I have had the opportunity to ask my questions regarding various aspects of the study and my questions are answered to my satisfaction. I, the undersigned agree to participate in this study and authorize the collection and disclosure of my personal information for dissertation and publication only.

Signature or thumb impression of the subject:

Date:

Name and signature of the witness:

Date:

Name and signature of person obtaining consent

Date:

## ರೋಗಿಯತಿಳುವಳಿಕೆಸಮ್ಮತಿನಮೂನೆ

ಸಂಶೋಧಕರ ಹೆಸರು: ಶ್ರೀನಾಥ್ ರೆಡ್ಡಿ ಕೆ

ಸಂಸ್ಥೆಯ ಹೆಸರು: ಆರ್.ಎಲ್ಲಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರ -

ಶ್ರೀದೇವರಾಜ್ ಅರಸ್ ಮೆಡಿಕಲ್ ಕಾಲೇಜ್‌ನಲ್ಲಿ ಸೇರಿಕೊಂಡಿದ್ದಾನೆ.

ಪಾಠೋಕ್ತವವರ ಹೆಸರು: ಕ್ರಮಸಂಖ್ಯೆ :

ನಾನುಶ್ರೀ /ಶ್ರೀಮತಿನನಗೆ ಆರ್. ಎಲ್. ಜಲಪ್ಪಆಸ್ಪತ್ರೆಯಲ್ಲಿ ನಡೆಸಲಾಗುತ್ತಿರುವ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನನ್ನು

ಸೇರಿಸಲ್ಪಡಲಾಗುವುದು ಎಂದು ನನಗೆ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ.

ಈ ಸಂಶೋಧನಾ ಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುನನ್ನನ್ನುಆಹ್ವಾನಿಸಲಾಗಿದೆ. ಈದಾಖಲೆಯಲ್ಲಿರುವಮಾಹಿತಿಯುಅಧ್ಯ

ಯನದಲ್ಲವಾಬ್ಬೊಳ್ಳಬೇಕೇಅಥವಾಬೇಡವೇಎಂಬುದನ್ನು ನಿರ್ಧರಿಸಲು ನನಗೆನೇರವಾಗುವುದು.

ಪ್ರಧಾನಸಂಶೋಧಕನೊಂದಿಗೆ ನಾನು ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನನ್ನ ಅನುಮಾನಗಳನ್ನು ಸ್ಪಷ್ಟಪಡಿಸಿ

ಕೂಂಡಿದ್ದೆನು.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವಂತೆ ನನಗೆ ಸೂಚಿಸಲಾಗಿದೆ ಏಕೆಂದರೆ ನಾನು ಅರ್ಹತಾ ಮಾನದಂಡಗಳನ್ನು ಪೂರೈ

ಸುತ್ತೇನೆ.

ನನ್ನ ರಕ್ತದ ಮಾದರಿಯನ್ನು ಗೊತ್ತುಪಡಿಸಿದವರೇಡ್ಡ್‌ಗಳಿಗೆನಿರ್ವಹಿಸಲಾನಾಡು.ಹಂಸಬಿಟಿ ಅವರನ್ನು ವಿನಂತಿಸು

ತ್ತೇನೆ ಮತ್ತು ಅಧಿಕಾರವನ್ನು ನೀಡುತ್ತೇನೆ. ಕೆಳಗಿನ ನನ್ನ ಸಹಿಯು ಅರ್ಹ ಆರೋಗ್ಯ, ವೃತ್ತಿಪರರಿಂದ ಪರೀಕ್ಷೆಯ ಅನುಕೂಲ

ಲಗಳು,ಅಪಾಯಗಳು ಮತ್ತುಮಿತಿಗಳನ್ನು ನನ್ನ ತೃಪ್ತಿಗಿವಿವರಿಸಲಾಗಿದೆ ಎಂದು ನನ್ನಅಂಗೀಕಾರವನ್ನು ರೂಪಿಸುತ್ತದೆ

ಭಾಗವಹಿಸುವಿಕೆ ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದೆ ಮತ್ತು ಮಾದರಿಸಂಗ್ರಹಣೆಗೆ ಯಾವುದೇ ಹಣಕಾಸಿ

ನಪಾವತಿಯಿಲ್ಲ.

ಎಲ್ಲಾ ಪರೀಕ್ಷಾ ಫಲಿತಾಂಶಗಳನ್ನು ವೈದ್ಯಕೀಯ ಗೌಪ್ಯತೆಯೊಂದಿಗೆ ಪರಿಗಣಿಸಲಾಗುತ್ತದೆ ಮತ್ತು ಕಾನೂನಿನ ಅಗತ್ಯವಿ

ದ್ವರ ಹೊರತುಪಡಿಸಿಯಾವುದೇಹೊರಗಿನವರಿಗೆಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲ.

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ನನ್ನ ಗೌಪ್ಯತೆ ನಿರ್ವಹಿಸಲ್ಪಡುವವರೆಗೆ ವೈದ್ಯಕೀಯ ಪರೀಕ್ಷೆ,

ಪರೀಕ್ಷೆಯ ಮೌಲ್ಯಮಾಪನ ಅಥವಾ ಶಿಕ್ಷಣಕ್ಕಾಗಿ ನನ್ನ ಮಾದರಿಯನ್ನು ಬಳಸಲು ನನ್ನ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡುತ್ತೇನೆ.

ನಾನು ಈ ಅಧ್ಯಯನದಿಂದ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಿಂತೆಗೆದುಕೊಳ್ಳಲು ಮುಕ್ತವಾಗಿರುತ್ತೇನೆ ಮತ್ತು ಇದು ನನ್ನ ಮುಂದಿನ ಕಾಳಜಿಯನ್ನು ಬದಲಿಸುವುದಿಲ್ಲ ಎಂದು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.

ರೋಗಿಯ ಮಾಹಿತಿ ಪತ್ರವನ್ನು ನಾನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಪ್ರತಿಯನ್ನು ಸ್ವೀಕರಿಸಿದ್ದೇನೆ. ಈ ದಾಖಲೆಯಲ್ಲಿ ಒದಗಿಸಿದ ಮಾಹಿತಿ ಮತ್ತು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ಪರೀಕ್ಷೆ,

ಪ್ರಕ್ರಿಯೆ, ಸಂಬಂಧಿಸಿದ ಅಪಾಯ ಮತ್ತು ಪರ್ಯಾಯಗಳ ಬಗ್ಗೆ ನಾನು ಹೊಂದಿರುವ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು

ನನಗೆ ಅವಕಾಶ ಕಲ್ಪಿಸಲಾಗಿದೆ.

ಹೆಸರು ಮತ್ತು ಸಹಿ / ಹೆಬ್ಬರಳು ಗುರುತು

ದಿನಾಂಕ:

ಪೋಷಕರ / ಪಾಲಕರ ಹೆಸರು / ಹೆಬ್ಬರಳು ಗುರುತು

ದಿನಾಂಕ:

ಒಪ್ಪಿಗೆ ತೆಗೆದುಕೊಳ್ಳುವ ವ್ಯಕ್ತಿಯ ಸಹಿ

ದಿನಾಂಕ

Sno	UHID NO	Gender	study group	Age	Cough	Fever	Dyspnea	Anorexia	Loss of weight	Hemoptysis	Chest pain	Night sweat	HTN	IHD	Smoking	Family history of PTB	Pallor	Icterus	Cyanosis	Clubbing	L.N
1	761984	M	1	74	1	1	1	0	0	0	0	0	0	0	1	0	0	0	0	1	0
2	762059	M	2	45	1	1	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
3	699953	M	2	37	1	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0
4	699440	F	1	55	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
5	699741	F	2	39	1	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0
6	699573	F	2	43	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	764618	F	2	20	1	1	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0
8	728480	M	1	60	1	1	0	1	1	0	0	0	0	1	1	0	1	0	0	1	0
9	749255	M	2	45	1	1	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0
10	768707	F	2	36	1	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0
11	666310	M	1	40	1	1	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0
12	666271	M	2	35	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
13	671313	F	2	32	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
14	771768	M	1	58	1	0	1	0	1	0	0	0	0	0	1	0	0	0	0	0	0
15	772374	M	1	60	0	1	0	1	1	0	0	1	0	0	0	0	0	0	0	0	0
16	737999	M	1	60	1	1	1	0	0	0	1	0	0	0	1	0	0	0	0	0	0
17	700181	M	2	48	1	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0
18	667289	M	2	54	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	706978	M	2	26	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
20	709518	M	1	46	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0
21	658780	M	1	58	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0
22	691367	M	2	55	1	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
23	712116	M	2	18	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
24	630800	M	1	60	1	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0
25	713205	M	2	52	1	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0
26	690328	F	1	57	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
27	197406	M	2	86	1	0	1	0	0	1	0	0	0	0	1	0	0	0	0	0	0
28	710441	M	1	45	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0
29	714920	F	1	43	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0
30	194605	M	2	30	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
31	716527	F	2	38	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0

32	195147	F	2	21	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0
33	716837	F	1	40	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0
34	607503	M	2	20	0	1	0	0	0	0	1	1	0	0	0	0	0	0	0
35	594956	M	2	84	1	0	1	0	0	0	0	0	0	0	1	0	0	0	0
36	717225	M	1	67	1	0	1	1	1	1	0	0	0	0	1	0	0	0	0
37	717179	F	1	40	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
38	690328	F	2	60	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0
39	719574	M	1	46	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0
40	718090	M	2	37	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0
41	718972	M	2	26	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
42	718349	F	1	45	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0
43	719099	M	2	44	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0
44	707168	M	1	56	1	0	1	1	1	0	0	0	0	0	1	0	0	0	0
45	184891	M	2	30	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0
46	629511	F	2	21	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
47	701922	M	2	32	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0
48	721447	F	2	23	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
49	718394	M	1	56	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
50	563703	F	1	35	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
51	594956	M	2	24	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0
52	696705	M	2	22	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
53	703943	F	1	35	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0
54	651735	M	2	19	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0
55	704682	M	2	28	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
56	702488	F	2	20	0	1	0	0	0	0	1	1	0	0	0	0	0	0	0
57	706337	M	1	46	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
58	640106	M	1	29	1	0	0	1	1	0	0	1	0	0	0	0	0	0	0
59	701421	F	1	48	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0
60	702472	M	2	51	1	0	1	0	0	1	0	0	0	0	0	0	0	0	0
61	693781	F	2	23	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
62	858952	F	2	38	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0
63	708202	M	2	44	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0
64	707120	M	1	45	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0
65	704412	F	1	60	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0
66	708948	M	1	75	1	1	0	0	1	0	0	0	0	0	1	0	1	0	0
67	694445	M	2	63	1	0	1	1	1	0	0	0	1	0	1	0	0	0	0
68	701550	F	1	58	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0

69	706332	M	2	46	1	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0
70	640106	M	1	46	1	1	0	0	1	0	0	0	1	1	0	0	0	0	0	0
71	565446	F	2	30	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
72	697239	F	1	36	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
73	711038	M	2	40	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
74	668056	M	2	70	1	1	1	0	1	0	0	0	0	0	1	0	0	0	0	0
75	708983	F	2	28	1	1	0	0	1	0	0	0	1	0	0	0	0	0	0	0
76	737824	M	1	55	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
77	614091	M	2	67	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
78	720838	M	1	58	1	1	0	0	0	0	1	1	0	0	0	0	0	0	0	0
79	712116	M	2	32	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80	733288	F	1	48	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
81	739734	M	2	75	1	0	1	1	1	0	0	0	1	0	1	0	0	0	0	0
82	701468	M	1	41	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
83	644015	F	1	58	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0
84	726948	M	2	40	1	1	1	0	1	0	0	0	0	0	1	0	0	0	0	0
85	740293	M	1	45	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
86	709768	M	1	50	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
87	728564	M	2	30	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
88	732858	F	2	19	0	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
89	701897	F	1	80	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0
90	719574	M	1	35	1	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0
91	743962	F	2	60	1	0	1	1	1	0	0	0	1	0	0	0	0	0	0	0
92	741245	M	1	58	1	1	0	0	0	0	0	1	0	0	1	0	0	0	0	0
93	744641	M	2	58	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
94	745882	M	2	48	1	1	1	1	1	0	0	0	1	0	0	0	0	0	0	0
95	743174	F	1	62	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
96	746657	F	2	50	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
97	731315	M	1	66	1	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0
98	688020	M	1	54	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
99	749525	M	1	55	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
100	749255	M	2	45	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
101	749516	M	1	73	1	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0
102	644883	M	1	68	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
103	737999	M	1	60	1	1	0	1	1	0	0	0	1	0	0	0	0	0	0	0
104	633322	M	2	60	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
105	757089	M	1	90	1	1	0	0	0	0	0	0	0	0	1	0	0	0	1	0



106	711038	M	2	80	1	1	1	1	1	0	0	0	0	0	1	0	0	0	0	0
107	688020	M	2	70	1	0	1	0	0	0	0	1	0	0	1	0	0	0	0	0
108	550751	F	2	22	1	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0
109	721788	F	1	60	1	1	0	0	1	0	0	0	1	1	0	0	0	0	0	0
110	387810	F	2	76	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
111	718394	M	2	66	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
112	719574	M	1	55	1	1	1	0	0	0	1	0	0	0	1	0	0	0	0	0
113	727627	M	2	60	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
114	728364	F	1	57	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0
115	671953	M	2	38	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
116	533072	M	1	55	1	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0
117	723870	M	2	50	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
118	668056	M	1	69	1	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0
119	711803	F	2	65	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
120	876161	M	1	62	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0
121	431278	M	2	20	1	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0
122	725418	F	2	18	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
123	614091	M	1	54	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
124	723718	M	1	54	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
125	665962	M	2	25	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
126	426082	F	2	58	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
127	726481	M	2	70	1	1	1	0	0	0	0	0	0	0	1	0	0	0	0	1
128	694882	F	1	35	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
129	694882	F	2	66	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
130	688020	M	1	71	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
131	626526	M	2	33	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
132	734647	F	1	64	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
133	764763	M	2	44	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
134	723906	M	1	52	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
135	649116	M	2	42	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
136	667737	F	2	60	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
137	726948	M	1	40	1	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0
138	737588	M	1	75	1	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0
139	703887	M	1	56	0	0	1	1	1	0	1	0	0	0	0	0	0	0	0	0
140	799223	M	1	40	1	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0
141	817441	F	1	46	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
142	689443	M	1	82	0	0	1	0	0	0	0	0	0	0	1	0	0	0	1	0

143	852771	M	1	57	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
144	845885	M	2	38	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
145	869726	M	2	50	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
146	861149	M	1	61	1	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0
147	869390	F	2	64	1	0	1	1	0	1	0	0	0	0	0	0	0	0	0	0
148	858398	M	1	57	0	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0
149	854869	M	1	59	1	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0
150	831741	M	1	61	0	1	0	1	1	0	0	1	0	0	0	0	0	0	0	0
151	851525	F	1	65	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
152	868617	M	2	61	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
153	701468	M	1	72	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
154	631024	M	2	75	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0
155	747324	M	2	40	1	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0
156	876583	F	2	38	1	1	0	0	1	0	0	0	0	1	1	0	0	0	0	0
157	845860	M	1	58	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
158	525966	M	1	60	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
159	858952	F	1	38	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
160	870837	M	2	56	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
161	869186	F	1	70	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
162	870495	F	1	85	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0
163	691759	M	2	67	1	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0

Sno	UHID NO	Edema	Pulse	SBP	DBP	RR	Fibrosis	Cavitatory	Consolidation	Pl. effusion	Other	Hb	TC	N	L	FBS	PPBS	HbA1c	Side of lesion	Lung Fields	Radiological appearance
1	761984	0	92	110	70	17	0	1	0	0	0	15	4.6	47.5	40.2	190	211	8.3	1	3	4
2	762059	0	90	130	80	16	1	0	0	0	0	10	5.12	71	37.6	112	130	4.6	1	6	2
3	699953	0	84	100	70	16	1	0	0	0	0	13	9	70.8	30.2	92	130	5.2	3	6	2
4	699440	0	80	100	70	18	0	0	1	0	0	14	8	70.2	32.6	220	420	9.5	1	6	1
5	699741	0	98	120	80	16	0	0	0	0	1	14	6.1	90.3	31.8	133	135	5.4	2	6	5
6	699573	0	72	110	70	16	1	1	0	0	0	15	9.2	72.7	37.8	68	110	5.6	2	6	3
7	764618	0	98	130	70	18	0	0	0	0	0	15.7	8	75.8	36.6	90	126	5.4	4	4	6
8	728480	1	48	110	70	16	0	1	1	0	0	9	4.5	67.8	30	346	412	14.7	3	3	1
9	749255	0	92	120	80	16	0	0	1	0	0	13.9	9	57	27.1	110	122	5.8	3	3	1
10	768707	0	90	160	90	18	0	0	0	1	0	12	5	42.1	25	113	123	5.2	2	1	5
11	666310	0	80	120	80	18	0	1	1	0	0	14	5	54.7	25.9	464	578	16.1	3	3	1
12	666271	0	88	100	80	18	1	0	0	0	0	13.5	6.9	61.7	22.1	149	183	6.3	3	6	2
13	671313	0	88	110	70	16	0	1	0	0	1	14	0	72.4	39.8	96	179	6.1	1	6	5
14	771768	0	92	140	90	16	0	0	0	0	1	15.3	9.1	52.4	37.8	203	332	9.3	2	6	5
15	772374	0	88	120	80	18	0	1	0	0	0	13.9	7	76	32.8	220	420	9.5	1	3	4
16	737999	0	100	120	90	16	0	0	1	0	0	17	9	87.8	38.8	190	211	8.3	2	6	1
17	700181	0	88	140	90	18	0	0	0	0	0	15	8	68.2	29.3	133	135	5.4	4	4	6
18	667289	0	98	110	70	16	0	1	1	0	0	15	7	79.1	32.6	68	110	5.6	3	3	1
19	706978	0	83	110	70	20	0	1	0	0	0	12	8	76.4	35.2	90	126	5.4	2	6	4
20	709518	0	80	100	80	18	0	0	0	0	1	15	10	72.1	34.6	100	212	7.6	1	6	5
21	658780	0	80	110	70	22	0	1	0	0	0	12	10	65.4	14.1	225	349	12.5	3	3	4
22	691367	0	90	140	80	16	0	1	0	0	0	13	8	65.5	27.3	112	160	4.5	5	6	4
23	712116	0	80	110	60	18	0	0	0	0	0	10.5	8.6	79	9.5	116	178	5.1	4	4	6
24	630800	0	83	130	70	20	0	0	1	0	0	12	10	80.6	13.5	172	205	13	2	1	1
25	713205	0	80	130	70	16	0	0	1	0	0	15	9	78.3	35.5	123	140	6.2	2	1	1
26	690328	1	80	120	80	16	0	1	0	0	0	11	8	76.6	38.5	130	336	14.6	1	3	4
27	197406	0	40	110	70	18	0	1	1	0	0	11.2	6	85	31.3	112	156	5.9	3	3	1
28	710441	0	128	110	70	14	0	1	1	0	0	17	8	61.8	33.7	204	116	10.3	1	6	1
29	714920	0	48	140	90	22	0	0	1	0	0	13	9	58.5	46	123	233	10.6	2	1	1
30	194605	0	80	120	80	18	1	0	0	0	0	13	9	68.9	41.8	90	106	5.3	1	6	2
31	716527	0	74	130	90	16	1	1	0	0	0	13.3	8	55.4	40.1	98	110	5.6	3	6	3
32	195147	0	78	120	80	16	1	1	0	0	0	15.1	8	68.4	34.5	123	139	5.3	4	4	3
33	716837	0	80	100	60	18	0	0	1	0	0	14	9	86.6	38.5	211	355	12.7	1	3	1

34	607503	0	80	110	60	16	0	0	1	0	0	11	10	60.8	29.4	90	130	6	2	1	1
35	594956	0	98	110	70	18	1	0	0	0	1	16	8	81.6	41.3	96	156	6.4	3	6	2
36	717225	0	89	110	60	18	0	1	0	0	0	16	8	86.3	37.1	401	423	13.1	3	3	4
37	717179	0	80	110	70	16	0	1	1	0	0	15	9	58	40	198	256	9.8	2	1	1
38	690328	0	72	130	90	18	0	0	1	0	0	14	6	89.3	40.7	102	167	6.1	1	1	1
39	719574	0	82	110	70	20	0	0	1	0	0	11	10	86.4	42	232	301	7.6	2	6	1
40	718090	0	80	150	100	18	0	0	0	1	0	11	7.02	66.7	38.8	138	166	4.7	1	5	5
41	718972	0	82	150	80	16	1	0	0	0	1	10	10	55.9	35.8	109	177	5.1	2	6	2
42	718349	0	82	104	60	22	0	1	0	0	0	14.7	9	79	34	198	251	8.7	1	1	4
43	719099	0	70	140	70	16	0	1	0	0	0	14	8	70.4	26	89	145	5	1	6	4
44	707168	0	80	140	90	18	0	1	1	0	0	12	10	79	26.6	220	321	10.7	3	3	1
45	184891	0	84	110	70	16	0	0	0	0	1	14	9.2	71.6	39	96	170	6.9	2	6	5
46	629511	0	80	90	60	18	0	0	0	0	0	16	8.6	65.8	25.5	98	110	5.4	4	4	6
47	701922	0	80	110	70	20	1	0	0	0	0	12	5	76	39.2	112	190	5.2	1	6	2
48	721447	0	90	130	60	16	0	0	0	0	0	18.5	6.2	69.8	39.1	100	140	5.1	4	4	6
49	718394	0	82	140	90	16	0	1	0	0	0	14.4	6	67.1	39.9	172	205	13	3	1	4
50	563703	0	70	110	70	18	1	0	0	0	0	15.9	6.4	74.7	35.4	179	256	8.9	1	6	2
51	594956	0	82	120	80	16	1	0	0	0	0	12.5	6.65	74.6	39	89	147	4.1	2	6	2
52	696705	0	80	120	80	18	0	0	0	0	0	16.9	9.3	59.4	31.5	99	178	5.2	4	4	6
53	703943	0	88	120	80	30	0	1	0	0	0	11.2	7.78	57	32	209	289	7.6	1	2	4
54	651735	0	88	110	70	20	0	0	0	0	0	7.2	8	73	33.2	90	106	5.3	4	4	6
55	704682	0	108	120	80	22	1	0	0	0	0	12.2	10	82.2	30.5	98	110	5.6	2	6	2
56	702488	0	80	100	60	18	0	0	0	0	0	12	9	84.1	33.3	123	139	5.3	4	4	6
57	706337	0	92	115	70	18	0	1	0	0	0	16	8	67.6	33.4	221	241	10.1	3	3	4
58	640106	0	88	120	80	16	1	1	0	0	0	17	9	85	41.6	189	276	8.7	3	6	3
59	701421	0	98	122	70	24	0	1	1	0	0	11	12	50.4	44.6	220	360	14.5	3	3	1
60	702472	0	86	160	100	20	0	0	1	0	0	13	8	64	36	104	133	4.9	3	6	1
61	693781	0	86	130	80	20	0	0	0	0	0	10	14	27	36.5	109	119	5.4	4	4	6
62	858952	0	66	110	70	16	0	1	0	0	0	15	13	84.6	30.3	122	149	5.8	1	2	4
63	708202	0	84	60	50	24	1	0	1	0	0	12	11	74.1	20.4	117	156	6.1	3	3	1
64	707120	0	83	110	90	20	0	0	0	1	0	11	13.6	71.5	19.4	243	296	7.2	2	1	5
65	704412	0	80	120	100	16	0	1	1	0	0	9.2	20	74	36	238	218	13	3	6	1
66	708948	0	73	120	70	16	0	0	1	0	0	9.6	20	76	39	234	334	11.2	2	1	1
67	694445	0	80	160	90	16	1	0	0	0	0	14	11	63.3	45.5	106	149	5.8	1	6	2
68	701550	0	88	120	70	18	0	1	1	0	0	12	7.68	68.8	40	249	300	10.9	3	3	1
69	706332	0	86	100	60	18	0	0	1	0	0	13.4	9.93	75.4	47.3	94	136	4.9	3	3	1
70	640106	0	94	140	90	18	0	1	0	0	0	11	16	80	11.4	177	212	8.3	2	6	4

71	565446	0	80	60	40	16	0	1	0	0	0	14	11.8	65.2	41.4	93	127	5.4	2	1	4
72	697239	0	80	110	70	16	0	0	1	0	0	15.7	5.37	63.7	39.3	183	273	7.9	1	6	1
73	711038	0	88	90	70	18	0	1	0	0	0	12	13.8	60.8	33.3	109	111	5.3	2	6	4
74	668056	0	98	110	70	18	1	0	1	0	0	11	16	74.3	17.3	104	106	5.3	3	3	1
75	708983	0	82	160	90	18	0	1	0	0	0	15	10	64	25.3	220	250	6.4	1	2	4
76	737824	0	88	110	70	16	0	0	1	0	0	11	11.6	48	33.6	400	520	13.2	3	3	1
77	614091	0	80	110	70	16	1	0	0	0	0	13.8	9.46	79.2	41.7	112	166	4.9	3	6	2
78	720838	0	78	110	80	16	1	0	0	0	0	14.5	17	79.4	13.1	220	280	7.3	1	6	2
79	712116	0	98	170	100	18	0	0	1	0	0	11	8.74	67.4	23.2	97	129	4.2	2	1	1
80	733288	0	68	110	70	16	0	1	0	0	0	15.4	12	73.2	15.4	256	333	7.6	2	6	4
81	739734	0	57	160	100	16	1	0	1	0	0	15.4	8	71.7	36.2	86	134	4.3	3	3	1
82	701468	0	98	110	70	18	0	0	1	0	0	14.2	8	52.9	26.2	238	312	10.2	2	3	1
83	644015	0	78	130	90	30	0	0	1	0	0	14.9	9	91.2	32	320	359	12.8	3	3	1
84	726948	0	82	110	70	20	0	1	1	0	0	13.5	6	67.5	24.1	79	130	4.6	2	1	1
85	740293	0	90	140	80	22	0	0	0	0	1	12.1	10	76.4	12.3	199	273	8.8	1	1	5
86	709768	0	80	120	60	18	0	0	0	0	1	14.2	702	56.4	30.8	155	297	7.4	2	6	5
87	728564	0	72	140	90	18	0	1	0	0	0	12.1	10	67.7	39.3	107	119	5.3	1	2	4
88	732858	0	88	140	90	16	0	0	0	0	0	14.5	9	80.8	33.6	81	150	5.2	4	4	6
89	701897	0	62	110	70	24	0	1	0	0	0	13.4	8	68.7	33.2	221	262	11.2	3	3	4
90	719574	0	80	180	100	20	0	1	0	0	0	14.8	10	55.2	36.6	236	336	9.1	1	1	4
91	743962	0	62	190	70	20	1	0	1	0	0	11.5	9.2	50.2	36.7	82	126	4.2	3	3	1
92	741245	0	62	110	70	16	0	0	1	0	0	11.4	8.6	87.3	39.2	321	389	14.2	3	3	1
93	744641	0	88	120	90	24	1	1	0	0	0	10.3	5	80.7	33.9	112	133	6	1	6	3
94	745882	0	92	150	80	20	1	0	0	0	0	11.4	6.2	46.3	40.6	121	133	5.2	2	6	2
95	743174	0	82	110	70	16	0	1	1	0	0	13.1	6	66.8	41	346	540	13.9	3	3	1
96	746657	0	78	110	70	16	0	0	0	0	1	14.6	6.4	52.9	12.4	118	189	6.3	2	6	5
97	731315	0	88	120	70	16	1	1	0	0	0	16.7	5.4	60	46.1	234	335	11.5	3	3	3
98	688020	0	82	110	70	18	1	1	0	0	0	16.6	5.4	64.2	25.6	345	546	12.4	3	3	3
99	749525	0	88	120	80	18	0	0	0	0	1	14.5	10	72	44.5	264	321	8.8	2	1	5
100	749255	0	68	110	70	18	0	1	1	0	0	16	10	89.3	44.6	106	117	5.4	1	1	1
101	749516	0	88	140	90	16	0	1	1	0	0	13	7	75.6	15.8	264	321	13.6	3	3	1
102	644883	0	86	120	80	16	0	0	0	0	1	16	7	94.9	41.4	229	341	11	1	6	5
103	737999	0	100	220	80	18	1	1	0	0	0	11	7.6	69.4	18.6	278	412	12.3	3	3	3
104	633322	0	86	140	90	18	0	0	1	0	0	16	10	58.9	26.6	104	139	5.2	2	1	1

1 0 5	75708 9	0	80	130	80	1 8	0	1	1	0	0	11	12	73.7	38	42 1	467	14. 3	3	3	1
1 0 6	71103 8	0	78	140	90	1 6	0	0	1	0	0	14. 4	8	89	44.5	10 9	111	5.3	3	3	1
1 0 7	68802 0	0	78	130	80	1 6	1	0	1	0	0	12	7	91.5	33	10 4	106	5.3	3	3	1
1 0 8	55075 1	0	86	120	80	1 6	0	0	0	0	0	16	7.1 4	50.2	37	22 0	250	6.4	4	4	6
1 0 9	72178 8	0	76	170	90	1 8	0	1	1	0	0	16	6	72	20.8	19 8	308	12. 7	3	3	1
1 1 0	38781 0	0	90	120	80	1 6	0	0	1	0	1	12. 8	7	69.4	38.8	10 8	155	5.5	3	3	1
1 1 1	71839 4	0	66	130	90	1 6	1	0	0	0	0	14	10	81.9	37.5	11 0	142	5.1	1	6	2
1 1 2	71957 4	0	54	120	80	1 8	1	0	0	0	0	10	12	85.5	36.5	20 9	229	8.9	2	6	2
1 1 3	72762 7	0	83	140	70	1 8	1	1	0	0	0	16	13	75.9	35.5	11 4	144	5.2	3	6	3
1 1 4	72836 4	0	80	120	80	1 8	0	0	0	0	1	16	9	66.5	36	23 1	354	9.7	1	1	5
1 1 5	67195 3	0	80	110	70	1 6	0	0	1	0	0	14	11	83.2	33	95	140	5.4	3	1	1
1 1 6	53307 2	0	84	130	90	1 6	0	0	0	0	0	16. 2	20	83.1	34	27 7	300	7.8	4	4	6
1 1 7	72387 0	0	88	110	70	1 6	1	0	0	0	0	11	6.6 5	90	45.9	97	136	5.9	2	6	2
1 1 8	66805 6	0	82	130	70	1 6	1	0	0	0	0	10. 5	9.3	80.7	42.7	22 2	280	9.3	3	3	2
1 1 9	71180 3	0	82	120	80	1 8	1	1	0	0	0	10	7.7 8	73.9	36	10 6	156	5.7	1	6	3
1 2 0	87616 1	0	74	140	90	1 8	0	1	1	0	0	10	8	61.7	35.5	23 4	243	11. 3	3	3	1
1 2 1	43127 8	0	86	130	90	1 6	0	0	0	0	0	10	12	50.3	33.7	11 2	160	4.5	4	4	6
1 2 2	72541 8	0	56	90	60	2 2	0	0	0	0	0	14	9.1	61.7	39.6	80	180	5.7	4	4	6
1 2 3	61409 1	0	82	110	90	2 0	1	0	0	0	0	11	9	79.9	32.7	18 6	273	7.7	1	6	2
1 2 4	72371 8	0	90	110	70	1 8	0	0	1	0	0	16	17	88	35.5	29 8	362	8.3	2	1	1
1 2 5	66596 2	0	65	90	70	1 6	0	0	0	0	0	12	12	87.2	39.6	11 0	136	5.8	4	4	6
1 2 6	42608 2	0	82	110	60	1 8	1	0	0	0	0	12	16	87.7	37.3	81	110	5.6	3	6	2
1 2 7	72648 1	0	68	120	80	1 6	1	0	1	0	0	18	10	86.6	39.2	66	114	5.8	3	3	1
1 2 8	69488 2	0	82	90	70	1 6	0	0	0	0	0	14	10. 3	81.2	12.3	17 8	212	7.6	4	4	6
1 2	69488 2	0	80	110	70	1 6	1	0	1	0	0	16	12	80.5	39.2	10 6	139	6.3	2	6	1

9																					
1 3 0	68802 0	0	82	140	90	1 6	0	1	1	0	0	15	10	98.4	33.8	34 5	546	12. 4	3	3	1
1 3 1	62652 6	0	80	140	90	1 6	0	0	1	0	0	14	16	72.6	38.9	11 3	153	5.3	1	1	1
1 3 2	73464 7	0	82	110	70	1 4	0	1	0	0	0	15	18	82.8	38.7	24 2	345	11. 6	3	1	4
1 3 3	76476 3	0	62	130	90	1 6	1	0	0	0	0	13	10	72.6	39.2	12 9	167	5.8	1	6	2
1 3 4	72390 6	0	98	130	90	1 6	0	1	1	0	0	16	7.1 4	93.6	34.2	20 9	299	7.9	2	6	1
1 3 5	64911 6	0	55	90	70	1 8	1	0	0	0	0	18	9.4 4	80.6	36.5	10 1	163	5.4	2	6	2
1 3 6	66773 7	0	52	130	90	1 6	1	0	0	0	0	17	14	75	36.2	88	146	5.6	3	6	2
1 3 7	72694 8	0	82	180	10 0	2 2	1	0	0	0	0	14	20	70.5	40.7	20 0	300	7.3	1	6	2
1 3 8	73758 8	0	62	130	80	1 6	0	1	1	0	0	18	12	79.3	41.5	33 2	229	11. 5	3	3	1
1 3 9	70388 7	0	82	130	80	1 8	0	0	0	0	1	16	6	69.4	41.3	23 4	332	9.2	2	1	5
1 4 0	79922 3	0	80	170	11 0	1 8	1	1	0	0	0	14	11	76	37	22 2	256	8.4	3	6	3
1 4 1	81744 1	0	98	122	80	1 8	1	0	0	0	0	17	6	72	34.5	29 4	302	7.7	2	6	2
1 4 2	68944 3	0	82	160	90	1 6	1	1	0	0	0	17	7	41	43.5	56 4	678	15. 3	3	3	3
1 4 3	85277 1	0	86	110	70	1 6	1	1	0	0	0	14	7	90.4	5	19 9	359	9.4	1	6	3
1 4 4	84588 5	0	90	110	70	1 6	1	1	0	0	0	14	12	87.1	10.7	18 1	198	7.5	1	6	3
1 4 5	86972 6	0	86	120	80	1 6	0	1	0	0	0	15	5.1 2	57.5	23.3	11 4	156	5.9	3	6	4
1 4 6	86114 9	0	86	140	90	1 6	0	0	0	0	1	18	18	60.8	30.8	23 0	327	9.9	2	1	5
1 4 7	86939 0	0	88	110	70	1 6	1	0	0	0	0	16	12	87.5	34.4	84	116	6.1	2	6	2
1 4 8	85839 8	0	90	130	90	1 6	1	0	0	0	0	13	8	43.5	28.2	29 7	348	8.7	3	3	2
1 4 9	85486 9	0	90	130	70	2 2	0	1	0	0	0	13	14	93.5	2.7	29 0	333	9.3	3	3	4
1 5 0	83174 1	0	82	130	90	1 8	1	1	0	0	0	15	12	92.4	33.9	26 0	293	8.1	3	3	3
1 5 1	85152 5	0	90	120	80	1 8	0	0	0	1	0	10	18	50	38.5	20 1	209	7.9	1	3	5
1 5 2	86861 7	0	76	110	70	1 6	0	0	0	0	1	14	9	68.3	16.1	11 9	176	6.4	1	6	5
1 5 3	70146 8	0	90	120	80	1 6	1	1	0	0	0	14	11	94.8	29	24 3	321	7.3	1	6	3

1 5 4	63102 4	0	86	130	80	1 6	1	0	0	0	0	14	9	83.5	39.2	10 3	136	5.3	2	6	2
1 5 5	74732 4	0	88	110	70	1 6	1	0	1	0	0	14	7.6	65.1	23.8	98	166	5.6	3	6	1
1 5 6	87658 3	0	82	120	80	1 6	1	1	0	0	0	11	6	90.6	36.7	12 3	139	5.3	1	6	3
1 5 7	84586 0	0	84	100	70	1 6	1	1	0	0	0	13	10	90.2	8.5	31 2	403	12. 7	3	3	3
1 5 8	52596 6	0	86	120	80	1 6	0	0	1	0	0	9.7	8	36.6	37.4	34 2	444	10. 4	2	1	1
1 5 9	85895 2	0	55	110	70	1 6	1	1	0	0	0	14	10	91.3	31.5	19 8	250	8.4	2	6	3
1 6 0	87083 7	0	82	110	70	1 6	1	0	0	0	0	14	12	86.7	39.2	92	134	4.9	1	6	2
1 6 1	86918 6	0	72	120	70	1 6	0	1	1	0	0	11. 6	9	64.4	28.5	23 1	298	11. 1	3	3	1
1 6 2	87049 5	0	88	120	80	1 4	1	0	0	0	0	12. 1	9	67.5	39.2	29 8	355	9.6	2	6	2
1 6 3	69175 9	0	83	130	80	1 6	1	1	1	0	0	13. 6	12	73.6	37.5	19 6	279	9.9	3	6	1

#### KEY OF THE MASTER SHEET:

Name of the variable	Key of the variable
Study Group	1=Diabetic, 2= Non-Diabetic
Cough, fever, Dyspnea, anorexia, loss of weight, hemoptysis, chest pain, night sweats, HTN, IHD, Smoking, family history of PTB, Pallor, icterus, Cyanosis, clubbing, LN, edema, fibrosis, Cavitatory, consolidation, pl. effusion, others	0= No, 1=Yes
Side of lesion	1=R, 2=L, 3=b/l, 4=Normal, Upper=5
Lung fields	1=lower, 2=middle, 3=Multilobar, 4= normal, 5= P.ef., 6=others
Radiological appearance	1=Consolidation, 2=Fibrosis, 3= Fibrocavitatory, 4=Cavitatory, 5=Others, 6=normal



