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A Comprehensive Study on the Modern Approaches to the Instrumental and Laboratory Diagnostics of Chronic Obstructive Pulmonary Disease in the Practice of GPs from the point of view of Evidence-based Medicine

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Abstract

Background: Chronic Obstructive Pulmonary Disease (COPD) is a progressive, life-limiting respiratory condition and a leading cause of global morbidity and mortality. Despite advances in treatment, underdiagnosis and misdiagnosis remain prevalent, especially in primary care. As clinical symptoms often overlap with other respiratory and cardiac conditions, modern evidence-based diagnostic tools—including laboratory and instrumental methods—are essential for early detection, proper staging, and management of COPD.

Methods and Materials: This study applied a comprehensive literature review method, analyzing data from global health guidelines (GOLD 2024, WHO), peer-reviewed journals, and clinical databases. Diagnostic tools investigated include sputum analysis, alpha-1 antitrypsin deficiency (AATD) testing, pulmonary function tests (PFTs) including spirometry and pulse oximetry, and radiographic imaging such as chest X-rays and computed tomography (CT). Emphasis was placed on evaluating diagnostic sensitivity, specificity, and real-world application in general practice.

Results: Sputum analysis was shown to be highly sensitive and specific for identifying bacterial and viral pathogens during COPD exacerbations. AATD testing identified a genetic component of COPD critical for tailoring patient management. Spirometry emerged as the gold standard for airflow obstruction diagnosis, with FEV1/FVC ratios below 0.7 being confirmatory. Imaging via CT and X-ray provided valuable information for disease staging and differentiating COPD from comorbidities. Collectively, these modern diagnostic tools significantly enhanced the accuracy of COPD diagnosis and informed more precise treatment decisions.

Conclusion: The integration of laboratory and instrumental diagnostics, guided by evidence-based medicine, is essential for timely and accurate diagnosis of COPD in general practice. Modern approaches such as sputum analysis, AATD screening, spirometry, and imaging significantly improve disease identification, reduce diagnostic errors, and support early intervention. These methods ultimately contribute to improved patient outcomes, reduced hospitalization, and better quality of life for COPD patients.

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Keywords: *COPD diagnostics*, *Spirometry*, *Alpha-1 antitrypsin deficiency*, *Sputum analysis*, *Evidence-based medicine*

Section 1: Project Definition

Project definition: I propose to conduct and summarize a comprehensive study of the modern approaches to the instrumental and laboratory diagnostics of chronic obstructive pulmonary disease in the practice of GPs from the point of view of evidence-based medicine and to explain and provide sufficient knowledge on the topic. In this research work, the modern approaches to the instrumental and laboratory diagnostics of chronic obstructive pulmonary disease (COPD) in the practice of general practitioners from the point of view of evidence-based medicine are discussed. This study also analyzes and estimates the sensitivity and specificity of different laboratory tests and instrumental investigations of COPD from the point of view of evidence-based medicine.

Project setting: This project involves reading and collecting data from the Internet and various sources, such as guidelines from the Global Initiative on Chronic Obstructive Lung Disease (GOLD), the World Health Organization (WHO), and several other international health organizations.

Project relevance and rationale: The comprehensive study on the project topic – modern approaches to the instrumental and laboratory diagnostics of chronic obstructive pulmonary disease in the practice of GPs from the point of view of evidence-based medicine – is important as these would be the updated and modern approach to diagnosing chronic obstructive pulmonary disease (COPD). To be able to identify and accurately diagnose COPD, the appropriate modern approaches are needed. Knowing, understanding and using the appropriate ways to diagnose COPD is essential since it provides timely identification of COPD cases and differentiates it from other respiratory diseases. Only a proper COPD diagnosis would improve management and prevent disability, along with the patient's life expectancy and quality of life, if the treatment is prescribed correctly.

It is important to understand and learn the methods of the instrumental and laboratory investigations of COPD and know how to interpret the results to appropriately analyze the obtained results to accurately and efficiently diagnose COPD apart from just relying on a diagnosis based only on clinical symptoms. As COPD is the fourth leading cause of death in the world, timely diagnosis of COPD provides efficient treatment and management of the patient, prevents the patient's disability, along with the prevention of COPD complications and improves the patient's life expectancy and quality of life.

Project Objectives: The main objectives of this study are to search and collect data from different journals and articles about the modern approaches to laboratory and instrumental investigations of COPD from the point of view of evidence-based medicine. Comparative and statistical analyses are also done. The final objective of this research work is to

compose a conclusion and formulate a proper diagnosis for COPD from the point of view of evidence-based medicine.

Project Methodology: The materials used in this study were extracted from PubMed, reports from GOLD, and articles posted by WHO. Several other articles, books, and journals were also referred to, and the Merck Manual was used.

Project Research Methods: This study used various databases, critical reviews, and comprehensive analyses of journals, articles, and books. Data were analyzed according to articles released by the Global Initiative on Chronic Obstructive Lung Disease (GOLD) and the World Health Organization (WHO).

Project Timetable:

Week 1: Selecting project topic, defining the project scope, and preparing a concept draft, which includes definition and rationale.

Week 2: Defining objectives, methodology, and research methods for the project topic. Finalizing project concept.

Week 3: Begin with a comprehensive study of the project topic.

Week 5: Finish research and compile information on the project topic.

Section 2: Final Project Overview

To conclude, the approaches to the instrumental and laboratory diagnostics of COPD in the practice of general practitioners from the point of view of evidence-based medicine, such as the methods discussed above, of sputum analysis, alpha-antitrypsin1 deficiency tests, pulmonary function tests and radiographic imaging tests (CXR and CT), are used in the modern days. The diagnostic value of these tests is high, and they are specific and sensitive to diagnose COPD in patients. These tests also aid in timely and effective treatment, preventing exacerbations and worsening of symptoms and conditions of the patient. These diagnostic investigations could also provide a more accurate diagnosis as they rule out other differential diagnoses, such as cardiac or skeletal. It provides information for the staging of the disease and the knowledge of the appropriate management tactics for the patient. The earlier COPD is diagnosed, the earlier the treatment can be administered. Disabilities and comorbidities could be avoided when COPD is diagnosed early, and treatment is prescribed correctly.

Only proper COPD diagnosis with appropriate diagnostic laboratory and instrumental investigations can improve the management of the disease and prevent disease complications, hence improving the patient's life expectancy and quality of life.

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Section 3: Updated Research Summary

3.1 Laboratory investigation of sputum analysis in patients with COPD

Sputum analysis in COPD patients is crucial to the diagnosis of COPD, especially when it comes to exacerbation of the disease. The most common findings during COPD exacerbations are increased airway inflammation, increased mucous production, and noticeable gas trapping. They are typically caused by various infections, environmental factors such as pollution, or another underlying lung-related issue [5]. The severity, type, frequency and suspected causes of COPD exacerbations should be closely followed up to formulate a better treatment and prevent further disabilities for the patient [6].

The coughed-up fluid that consists of saliva and mucous from the respiratory tract, often after an infection or irritation of the mucosa of the respiratory tract, is known as sputum. Sputum analysis has a crucial role due to its contents, including various cells and molecular compounds, such as soluble lipids and proteins. It is a noninvasive method; however, when the patients have difficulty expelling sputum, sometimes a more invasive method may be used. Sometimes, physiotherapy maneuvers may be helpful to collect sputum from the patient. Sputum is usually collected in a sterile and sealed container early in the morning before eating or drinking. After rinsing the mouth, clear water removes contaminants in the oral cavity for a more accurate result. For patients with difficulties in sputum expectoration, a nebulized hypertonic saline solution is given to stimulate coughing and liquefy the mucous. At times, bronchoscopy could collect sputum samples in situations such as persistent infections, cough, or unusual findings in imaging tests. The sputum specimen is analyzed macroscopically and microscopically [7].

When a smear is received, sputum volume, the presence or absence of sputum purulence, and the sputum's colour are noted [6, 8]. When bacterial colonization or infection is present, the sputum is yellow, green, or yellowish green, an indicator of neutrophils in the sputum [8]. A smear is initially done when the sputum specimen is collected for Gram staining to identify the bacteria that could be causing the exacerbation of COPD. Gram-positive bacteria stain crystal violet, whereas gram-negative bacteria stain red or pink with a counterstain. An acid-fast bacilli stain is done when tuberculosis is suspected [7]. Sputum culture is necessary for hospitalized patients but not for outpatients. Outpatients usually have the sputum culture result in the microorganisms of gram-positive diplococci (Streptococcus pneumoniae), gram-negative bacilli (Haemophilus influenzae), or both. The findings of microorganisms in the sputum culture of hospitalized patients are resistant gram-negative organisms such as Pseudomonas or, rarely, Staphylococcus [8]. A review was conducted to show the specificity and sensitivity of sputum Gram stain [9].

Table 1: Review of sensitivity and specificity of sputum Gram stain [9]

Microorganisms	Sensitivity (%)	Specificity (%)
Streptococcus pneumoniae	59	87
Haemophilus influenza	78	96
Staphylococcus aureus	72	97
Gram-negative bacilli	64	99

In conclusion, it is sensitive and highly specific for identifying pathogens in the sputum Gram stain test. Hence, it is an appropriate test to determine the microorganisms of secondary infection that cause exacerbations in COPD patients.

Respiratory viruses can also be identified in sputum specimens in patients with COPD via viral testing by nasopharyngeal swabs or nasal washes. However, some viral pathogens, such as H1N1 influenza and severe acute respiratory syndrome (SARS) coronaviruses, are not detected in upper airway secretions. In this case, real-time polymerase chain reaction (RT-PCR) is also used to detect secondary infections by respiratory viruses in COPD patients [7]. Respiratory syncytial virus (RSV), rhinovirus, and metapneumovirus can be detected via a respiratory viral panel, which may help formulate antimicrobial therapy. A rapid influenza test is done during influenza season, which would guide treatment with anti-influenza agents. Testing for COVID-19 is also indicated [8].

Sputum analysis could also determine the presence of abnormal cells. It provides identification of lung cancer cells and non-cancer cellular and acellular materials, which could be useful in differentiating other lung diseases from COPD. The hematoxylin and eosin (HE) stain is the gold standard for sputum analysis for suspected lung cancer cases. Other stains, such as the Wright, Giemsa, and Wright-Giemsa mixed stains, are used for differentiating different blood cell types, which are indicators of lung infection [7]. In COPD, neutrophilia without eosinophilia is sometimes found. When eosinophilia is detected in COPD, it could be due to cigarette smoking or other causes [10].

3.2 Laboratory investigation of antitrypsin one deficiency in patients with COPD

Alpha antitrypsin-1 (AAT) protein, also known as alpha-1 proteinase inhibitor or alpha-1 protease inhibitor, along with alpha-1 antichymotrypsin, C1 inhibitor,

antithrombin, neuroserpin and others, are part of a superfamily of the serine protease inhibitor (serpin). AAT can strongly inhibit neutrophil elastase, an enzyme released during inflammation and infection. Hence, it is known as the major anti-elastase of the lower respiratory tract. Moreover, AAT can also modulate immunity, proteostasis, apoptosis, inflammation, and possibly cellular senescence programs [11, 12].

The systemic deficiency of AAT, also known as the alpha-antitrypsin1 deficiency (AATD), is caused by a rare mutation in the SERPINA1 gene, which could be inherited through autosomal codominant transmission, leads to liver failure and chronic lung disease such as emphysema [5, 12, 13]. SERPINA1 is the gene that encodes AAT at the long arm of chromosome 14. The commonest and normal allele in the SERPINA1 gene is the "M" allele. When an individual possesses two copies of the M allele (MM), it leads to a decreased level of AAT. The S allele leads to a moderately low level of AAT, while the Z allele leads to a significantly low level of AAT. Patients who carry two copies of the Z allele (ZZ) will be very likely to have AATD, and the combination of SZ alleles is more likely to develop lung diseases, particularly when they smoke [13].

Patients who have AATD will experience a reduced level of functional AAT in blood and lungs as the deficiency is due to the impaired production of AAT, leading to the destruction of alveoli by neutrophil elastase and, in the end, leads to emphysema and bronchiectasis. In the liver, the deficiency in AAT will lead to protein accumulation, which results in liver damage [13]. The severity of AATD and risk factors of emphysema varies depending on the following factors such as tobacco smoke, chemicals, dust, parental history of COPD, personal history of BA, chronic bronchitis or pneumonia and infections [5, 13, 14].

Laboratory investigations for AATD are carried out in COPD patients, as the clinical presentation of lung diseases associated with AATD shares various similarities with COPD. Most COPD and AATD patients are smokers, and smoking exacerbates both conditions. In patients under 50 years old with symptomatic COPD and patients who have COPD and do not smoke despite their age are tested for AATD [8, 15]. Identification of biallelic pathogenic variants in the SERPINA1 gene or detection of a functionally deficient AAT protein variant by protease inhibitor (PI) typing will provide a result of low serum concentration of AAT and lead to a diagnosis of AATD [13]. In patients with a family history of premature COPD or unexplained liver disease, more predominant lower lobe distribution of emphysema, and COPD associated with antineutrophil cytoplasmic antibody (ANCA)-positive vasculitis, AATD is highly suspected, and the genetic testing of AATD is done [8].

3.3 Instrumental diagnostics by performing PFT in patients with COPD

Pulmonary function tests (PFTs) are extremely helpful in diagnosing, staging, and monitoring COPD. A basic PFT includes spirometry and pulse oximetry [18]. In a PFT,

measurements of airflow, lung volumes, gas exchange, responsiveness to bronchodilators, and respiratory muscle functions are obtained. Both spirometry and pulse oximetry are noninvasive, cheap, and easily available [6].

Forced spirometry provides quantitative measures of the flow of inspiration and expiration. The nose is closed with nose clips for a more accurate result. For inspiratory flow and volume measurements, the patient is asked to fully exhale as much as possible and then inhale. The maximum amount of air breathed in one deep breath is the peak inspiratory volume, and the volume breathed in per second is the inspiratory flow. On the other hand, to determine the expiratory flow and volume, the patient is asked to inhale as much as possible and exhale the best they can into an apparatus that records the expiration. The exhaled volume is recorded as forced vital capacity (FVC), and the volume exhaled in the first second is recorded as the forced expiratory volume in one second (FEV1). Also, the peak expiratory flow (PEF) is provided [19].

To appropriately diagnose COPD, FEV1 and FVC are both important. The most repeatable flow metric, FEV1, is particularly helpful in identifying and tracking patients with obstructive lung diseases, such as bronchial asthma (BA) and COPD. FEV1 and FVC are extremely useful in identifying obstructive and restrictive lung diseases. Restrictive lung disease is excluded when a normal FVC result is obtained. When an obstruction is present, a decrease in the ratio of FEV1 to FVC is detected. To differentiate COPD and BA, a repeat measurement of FEV1 and FVC using short-acting bronchodilators is done [6, 19]. Before and after an inhaled bronchodilator is administered, spirometry is performed. Spirometry is performed, results are recorded, and then different inhaled bronchodilators are given, such as the short-acting beta2-agonists (SABA), short-acting muscarinic antagonists (SAMA), or a combination of both. After administering the bronchodilators, spirometry is repeated, and the result is recorded [5, 6, 16]. Ten to fifteen minutes after administering a short-acting beta agonist, thirty to forty-five minutes after administering a short-acting anticholinergic, or a combination of the two classes, FEV1 should be assessed [5].

SABA mimics catecholamines and acts as ligands to the adrenergic receptors with an increased selectivity towards the beta-2 adrenergic receptors. They bind with the beta-2 adrenergic receptors and activate them. The activation of these receptors leads to an increase in adenylyl cyclase, which causes an increase in intracellular cyclic adenosine monophosphate (cAMP) through the hydrolysis of adenosine triphosphate (ATP). This elevation of cAMP-dependent protein kinase A. PKA will then reduce or decrease the sensitivity of intracellular calcium ions in the airway smooth muscle cells, which prevents airway smooth muscle contraction [3]. SABA is preferred in this case due to its short onset of action. Hence, the result can be taken soon compared to the long-acting beta2-agonists (LABA). Within the cholinergic system, SAMA are competitive antagonists of the neurotransmitter acetylcholine at the receptor sites. Their function is to relieve dyspnea and bronchodilation [20]. Like SABA, anticholinergic drugs also have a long onset of action;

they are classified as long-acting muscarinic antagonists (LAMA). Antimuscarinic antagonists and beta2-agonists are also used in the treatment of COPD, apart from their usage for diagnostic purposes [6].

A normal spirogram will give the result of FEV1 as 4 litres, FVC as 5 litres, and the normal ratio of FEV1 to FVC is 0,8 [21]. Suppose the spirometry result shows an obstruction and provides the suspicion of COPD, with the result of FEV1 to FVC being less than 0,7. In that case, another spirometry is done after administration of short-acting bronchodilators [6, 16, 17]. The spirometry criterion for airflow obstruction for COPD given by GOLD is the postbronchodilator ratio of FEV1 to FVC is less than 0,7 [6, 22]. Spirometry could also provide information about the grades and severity of the disease in COPD patients where their FEV1 to FVC ratio is less than 0,7, according to GOLD. In grade one, mild severity, the FEV1 is less than or equal to 80% predicted. In grade two, moderate severity, the FEV1 is more than or equal to 50% and less than 80% predicted. In severe grade three, the FEV1 is more than or equal to 30% and less than 50% predicted. In the very severe stage of grade four, the FEV1 is less than 30% predicted [6, 8]. The sensitivity and specificity of spirometry for the upper respiratory tract are 88% and 84,4%, respectively [23].

Another test for PFT is pulse oximetry. It is a noninvasive and cheap method to measure oxygen saturation. As a screening technique to find individuals with underlying lung disease, track patients experiencing shortness of breath during exercise, and ascertain whether the patient is recovering from an exacerbation or has a stable underlying lung disease, pulse oximetry is crucial in diagnosing COPD. During a COPD exacerbation, pulse oximetry is also useful for assessing patients with acutely worsening symptoms, particularly dyspnea, to evaluate patients with severe disease, defined as FEV1 of less than 50% predicted, cyanosis, or cor pulmonale for possible respiratory insufficiency or failure, and determining the severity of the exacerbations [24]. Peripheral oxygen saturation determined by pulse oximetry in COPD patients is often less than 92% [6, 24]. The specificity and sensitivity of pulse oximetry are 84.6% and 83%, respectively [25].

3.4 Instrumental diagnostics by performing radiographic imaging tests in patients with COPD

According to GOLD 2024, a chest X-ray is valuable in excluding alternative diagnoses and identifying concomitant respiratory, skeletal, and cardiac diseases in COPD patients, even though it is not useful to establish a diagnosis in COPD [6]. Radiographic imaging tests include chest X-rays (CXR) and computed tomography (CT). Pulmonary emphysema, a progressive lung disease, is a form of COPD. COPD includes chronic bronchitis and emphysema; most patients have both chronic bronchitis and emphysema together [26].

Emphysema is the abnormal permanent enlargement of lung air spaces distal to the terminal bronchiole with the breaking down of their walls without fibrotic processes and the loss of elasticity in the lung parenchyma caused mainly by exposure to noxious gases such as cigarette smoking [26]. Chronic bronchitis is a course of productive cough for more than 3 months, happening within 2 2-year span, and it is often associated with cigarette smoking. It can also be caused by inhaled irritants to the respiratory tract, such as toxic chemicals, industrial pollutants and others. Repeated exposure to infections such as influenza types A and B, Staphylococcus, Streptococcus, and Mycoplasma pneumonia can also cause chronic bronchitis [27].

In COPD patients with emphysema, findings of CXR include hyperinflation, flattening of the diaphragm, a small heart, and possible bullous changes. On the lateral view, a “barrel chest” with an increased anterior-posterior diameter may be noted [16, 28]. The “saber-sheath trachea” sign may be present as well. It refers to the coronal narrowing of the intrathoracic trachea in the frontal view with the concomitant sagittal widening in the lateral view seen in CXR [28]. For COPD patients with chronic bronchitis, the CXR findings are not specific, such as increased bronchovascular markings, thickening of bronchial wall and cardiomegaly [16, 28]. Differentiating these findings from other cardiac diseases is crucial for treating COPD cases appropriately and efficiently. CXR is also often done to check for pneumonia secondary to COPD or pneumothorax. Pulmonary embolism could be ruled out via CXR as well [8]. The figure below shows the findings in imaging biomarkers and the pathophysiology of COPD exacerbation [29].

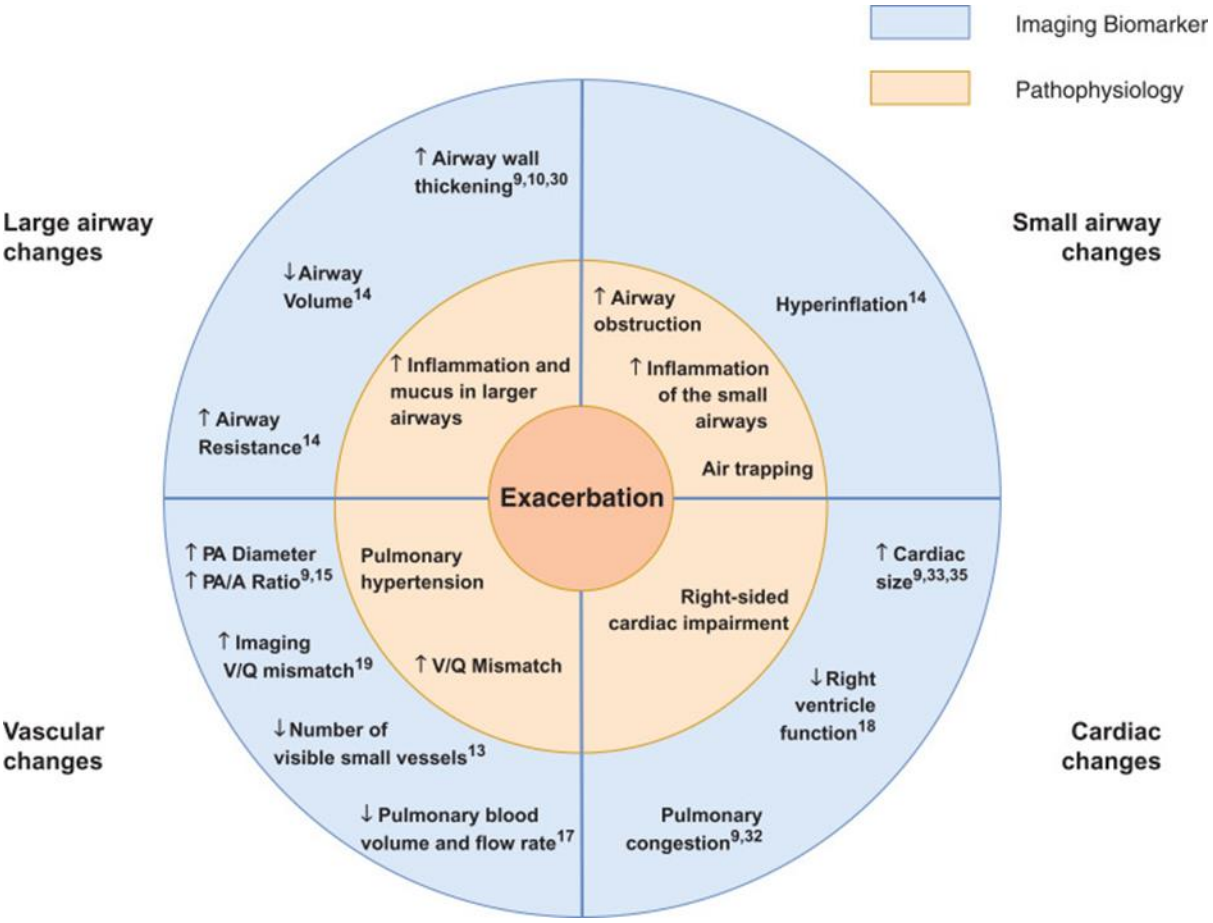

Figure 1: Pathophysiology and their corresponding imaging biomarker of COPD exacerbation.

As seen in the figure above, the increase in inflammation and mucous in larger airways in COPD exacerbation leads to an increase in airway wall thickening, an increase in airway resistance and a decrease in airway volume. The small airway changes are increased in airway obstruction and inflammation of the small airways with air trapping, which will be seen as hyperinflation in radiographic imaging tests. The vascular changes in COPD exacerbation show an increase in pulmonary artery (PA) diameter and the pulmonary artery to the aorta (PA/A) ratio in radiographic imaging tests. It also shows the increase in ventilation-perfusion (V/Q) mismatch and a decrease in the number of visible small vessels with the decrease of pulmonary blood volume and flow rate in the results of imaging test, which is due to pulmonary hypertension and the increase of V/Q mismatch. There are also cardiac changes found in COPD exacerbation. Right-sided cardiac impairment leads to findings such as pulmonary congestion, a decrease in right ventricular (RV) function, and an increase in cardiac size (cardiomegaly) [29].

Conversely, CT provides additional insights into the structure and pathophysiologic abnormalities present in COPD patients with emphysema and/or chronic bronchitis [6]. The finding for chronic bronchitis via CT is the thickening of the bronchial wall and enlarged vessels. Scarring with bronchovascular irregularity and fibrosis can be found if repeated inflammation is detected. Alveolar septal destruction and airspace enlargement, which may occur in various distributions, can be found in the CT result of emphysema. When emphysema is predominantly noted in the upper lobes, centrilobular emphysema is diagnosed. When it is predominantly noted in the lower lobes, panacinar emphysema is diagnosed. When emphysema often occurs near lung fissures and pleura of the lungs, paraseptal emphysema is diagnosed. Rupture of pleural blebs may lead to spontaneous pneumothorax or pneumomediastinum, whereas the formation of giant bullae may lead to compression of mediastinal structures [28]. CT imaging is helpful in patients with bronchiectasis, malignancy, or pulmonary embolism [8, 16]. CT imaging could also provide information about COPD comorbidities, such as coronary artery calcium, PA enlargement, bone density and muscle mass. It could rule out malignancy as well [6].

Section 4: Project Implementation Summary

COPD is often evaluated in patients with relevant symptoms and risk factors. However, laboratory testing is often required to complete the diagnosis. The laboratory investigations discussed below are sputum analysis and the test for alpha-antitrypsin1 deficiency (AATD). Different parameters of sputum analysis are discussed below, along with the interpretation of the results. In the subchapter on laboratory investigation of sputum analysis in patients with COPD, a general overview of sputum analysis is discussed. AATD and its pathophysiology are also discussed below in its own subchapter. Sputum analysis and genetic testing for AATD are crucial for timely and efficient treatment, improving patient life expectancy and quality of life, decreasing mortality and morbidity, and preventing unnecessary comorbidities, complications, and disabilities.

Instrumental diagnosis is more important than laboratory investigations in COPD diagnosis, staging, and monitoring. Diagnosis of COPD is often confirmed by pulmonary function test (PFT) through spirometry and pulse oximetry [16, 17]. Chest X-ray and computed tomography will be discussed below in this research work as imaging tests for patients with COPD. Apart from being able to diagnose COPD, PFT and imaging techniques help differentiate COPD from other lung diseases, sometimes even cardiac and skeletal diseases. The earlier COPD is confirmed as the diagnosis, the faster and more efficient the treatment will be, hence reducing hospitalization and readmission rates, reducing mortality, morbidity and disabilities in patients with COPD.

Section 5: Project Analysis, Evaluation, and Recommendations

The timely identification or diagnosis of COPD exacerbation is crucial as the condition can significantly impact a patient's health, increase readmission and hospitalization rates, and lead to disease progression [5]. Sputum analysis enables early detection of secondary infection and timely treatment according to the microorganism identified to improve the patient's life expectancy and quality of life.

Moreover, the identification of AATD in patients with COPD is important as it allows timely diagnosis and efficient treatment of both COPD and AATD. Standard COPD therapy, along with periodic intravenous infusions of AAT, is given to patients who have established emphysema and have AATD [14]. The earlier we manage to diagnose AATD in COPD patients, the earlier such therapy could be used to prevent further disabilities and comorbidities.

Meanwhile, with instrumental diagnoses, such as high specificity and sensitivity, that provide a high diagnostic value, PFT is important in diagnosing COPD.

Also, when CT imaging and CXR are taken together, they provide high diagnostic value for COPD patients in confirming COPD forms. These methods for diagnosing COPD in patients lower the risk of exacerbation and improve the patient's quality of life.

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