### ORIGINAL RESEARCH

# Prevalence of obstructive lung patterns and actual spirometric result at different workplaces in Ethiopia: A systematic review and meta-analysis





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### Abstract

Background and Aims: Burdens of occupational exposure like insoluble dust particles and chemicals in the respiratory tract leads to impaired clearance. This study aims to assess the prevalence of obstructive lung patterns and actual spirometric result in Ethiopia at different workplaces.

Methods: Five electronic databases such as: PubMed, HINARI, Science Direct, Google Scholar, and African Journals Online were searched in studies conducted from 2010 to 2021. In this study, we used STATA 14 software for data analysis and the quality of included studies were appraised using the New Castle Ottawa quality assessment tool. The pooled prevalence of obstructive lung patterns and actual spirometric results were estimated using effect size and standardized mean differences (SMD).

Results: A total representative of 3511 participants was included in this study. The pooled prevalence of obstructive lung patterns in occupational exposure at different workplaces was found 13.04% (95% CI: 7.96, 18.12,  $I^2$  = 89.2%). On the other hand, the pooled prevalence of obstructive lung patterns in controls was 4.10% (95% CI: 1.86, 6.34,  $I^2 = 76.8\%$ ). SMD of spirometric results was significantly decreased in cases as compared to the controls. The SMD of FVC in a litter (L) at 95% of CI: -0.50  $(-0.70, -0.30, l^2 = 87.7\%)$ , SMD of FEV<sub>1</sub> in (L) at 95% CI: -0.54 (-0.72, -0.36,  $I^2 = 84.9\%$ ), SMD of FEF<sub>25</sub>%-<sub>50</sub>% in litter per second (L/s) at 95% of CI: -0.42 (-0.67, -0.17,  $I^2 = 81.9\%$ ) and SMD of PEFR in L/s at 95% CI: -0.45 (-0.68, -0.21,  $I^2$  = 78.4%) were significantly decreased in cases as compared to the controls.

Conclusion: The pooled prevalence of obstructive lung pattern was higher in people who are working at different workplace that generating dusts and chemicals. The SMD of actual spirometric results were reduced in cases than controls. Therefore, to alleviate this problem appropriate preventive measure would be warranted for those people who are working in different dust and chemical generating environments.

### **KEYWORDS**

Ethiopia, obstructive lung pattern, prevalence, spirometry

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### 1 | INTRODUCTION

Organic and inorganic dusts contained in the air particles are inspired and accumulated in the lung conducting and respiratory zone throughout the respiratory system.<sup>1,2</sup> Occupational exposure of dusts and chemicals causes the deposition of particles in the respiratory tract affecting the ventilation capacity of the lung. The airway problem happens due to the inspired dust particles that cause obstructive lung patterns.<sup>3</sup> The obstruction of the small, medium and larger airways in the lung are mainly due to the dust containing air particle inhalation which leads to inflammation and excessive bronchial mucus secretion.<sup>4–7</sup> Occupational lung impairment develops due to the inhalation of dust and chemicals into the lung.<sup>1,8</sup>

Occupational exposure to cotton dust, wood dust, flour dust, household air pollution, and pesticides on sprayed fields impairs lung function. B-11 The lung develops airflow problems throughout the respiratory tract. Respiratory health problems like airflow limitation in the respiratory tract may be due to the destruction of elastic septal tissue (emphysema) of the lung resulting in air trapping and bronchial asthma due to causing bronchoconstrictionin turn decreases the oxygen content of body. 19,10,13

Several studies showed the association between the duration of occupational exposure and lung problems by spirometric results.  $^{2,14}$  Spirometry plays a fundamental role in medical surveillance investigation of occupational lung disease.  $^{15,16}$  Spirometer also plays a significant role to assess the lung functions in different occupational areas to determine resistive work of breathing.  $^{17,18}$  The forced expiratory volume in the first second (FEV<sub>1</sub>) to forced vital capacity (FVC) ratio <70% was the cut point for the airway problems.

In Ethiopia due to the expansion of different industries all over the country, occupational–related obstructive lung problems became public health issue that seeks different interventions to prevent the problem (8). Therefore, this systematic review and meta-analysis was designed to assess the prevalence of obstructive lung patterns and the actual spirometric results in different workplaces in Ethiopia.

### 2 | METHODS

### 2.1 | Registration and protocol

This review protocol is registered at the National Institute for Health Research; PROSPERO international prospective register of systematic reviews with registration number CRD 42022340753 at https://www.york.ac.uk/inst/crd records.

# 2.2 | Search strategy and study screening

A systematic review and meta-analysis of published studies was conducted to assess the obstructive lung patterns and spirometric results of the lung in different workplaces of Ethiopia. Five electronic databases such as: PubMed, HINARI, Science Direct, Google scholar,

and African Journals Online were searched cross-sectional articles published in English since 2010–2021. The search was done by using the following Medical Subject Heading (MeSH) terms; "prevalence," obstructive," "lung pattern," "spirometry," "work" AND Ethiopia" using separately or in combination (Supporting Information: Table S1).

Data was exported to reference management software (EndNote 6) and counted the total number of search item results. The titles, abstracts, and the full article were used to screen studies. All published articles were retrieved using their eligibility criteria. Those eligible articles were included in this review. The search process of the review was presented in Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA). The PRISMA flow chart clearly shows the included and excluded articles depending on the outcome variables. We rigorously followed the PRISMA guideline during the systematic review and meta-analysis process (Figure 1).

### 2.3 Characteristics of the outcome variables

The prevalence of obstructive lung patterns and actual spirometry results at different workplaces in Ethiopia was the key finding variables of this systematic review and meta-analysis.

Obstructive lung patterns: The forced expiratory volume in the first second (FEV<sub>1</sub>)/FVC ratio <70% and FEV<sub>1</sub> value <80% (percentage predicted values) were considered as obstructive lung patterns.<sup>6,19,20</sup> This study also explores the actual spirometry results being conducted at different workplaces such as; coffee processing factories, particle board workers, flour mill workers, cleaners, steel workers, cobblestone paving workers, textile factory workers, house fuel use, and agricultural workers to assess the status of the lung function.

### 2.4 | Inclusion and exclusion criteria

We observed the studies from an initial search to well-defined inclusion and exclusion criteria.

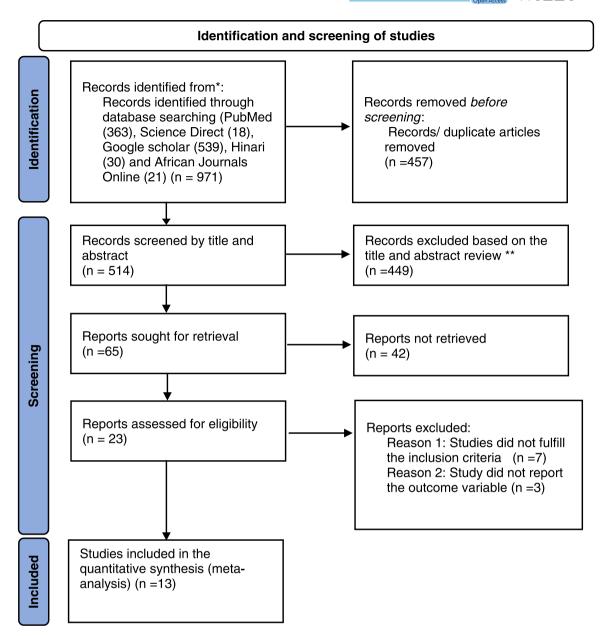
Study area: Research articles conducted in Ethiopia, were included.

Study period: Studies conducted until August 30, 2021 were included.

Study design: All comparative cross-sectional studies that contain original data reporting the obstructive lung patterns and actual spirometry results at different workplaces in Ethiopia were included.

Language: Literature published in English language were included.

Population: Studies were conducted among different dust exposure workers. The study article, which did not report the outcome interest were excluded after observing their full texts. Workers who had smoker's history and systemic disease like heart attack and tuberculosis were exclude from pulmonary function test. All study participants were nonsmokers.



**FIGURE 1** PRISMA diagram showing studies utilized for systematic and meta-analysis of the prevalence of spirometric analysis burden of COPD at different workplaces in Ethiopia at http://prisma-statement.org/prismastatement/flowdiagram.aspx.

### 2.5 Data extraction process

Two authors (D. D. and E. T.) independently conducted data extraction for those included studies using a standardized data extraction format prepared in Microsoft Excel. In the data extraction different outcome variables were extracted such as: the author, the region, publication year, study design, sample size, the prevalence of obstructive lung pattern in cases and controls, and type of occupational exposures were extracted. The data extraction format also included the FVC maneuver components of spirometric results conducted at different workplaces. Variables most frequently reported indicators of the original articles included in this systematic review and meta-analysis. Any difference in the two authors

during data extraction process was resolved through discussion (Supporting Information: Data S1).

### 2.6 | Quality assessment and protocol

Two authors (D. D. and E. T.) assessed the quality of the included studies. The authors used Newcastle-Ottawa Scale (NOS) quality assessment tool for appraising the qualities of the included studies. The tool has indicators consisting of three main sections; the first section has five stars and assesses the methodological quality of each study. The second section of the tool evaluates the comparability of

the studies. The last part of the tool measures the quality of the original articles concerning their statistical analysis. Using the tool as a protocol, the two authors independently evaluated the qualities of the included articles. The quality of the studies was evaluated using these indicators; those with medium (fulfilling 50% of quality assessment criteria) and high quality (6 out of 9 scales) were included for analysis. By taking the mean score of the two researchers, the consistencies of the assessment results were resolved (Supporting Information: File S1).

### 2.7 Measures of outcome interest

The primary objective of this systematic review and meta-analysis was to assess the pooled prevalence of obstructive lung patterns in different workplaces of Ethiopia. The second outcome of this study was evaluate the actual spirometric results of lung in people working in different places of Ethiopia.

### 2.8 | Data analysis

# 2.8.1 | Statistical analysis, risk of bias, and heterogeneity

In this review we used STATA version 14 software for the analysis of variables. The binomial distribution formula was computed for the estimation of the meta-analysis. To describe the pooled prevalence estimate, Meta-STATA command was computed considering the random-effect model or effect size (ES). The standard mean difference (SMD) of 95% confidence interval (CI) was used for the analysis of the actual spirometric results in different workplaces. SMD is the ratio of the mean difference to the pooled standard deviations of continuous data. The weight of each study is described by the size of each box, whereas the crossed line shows 95% CI. Publication bias was assessed through funnel plot. The sensitivity test was done to see the stability of the study results and subgroup analysis was conducted to determine the heterogeneity of studies.

### 3 | RESULTS

### 3.1 Study selection and characteristics

In this study, a total of 971 research articles were searched from records database. Among these 457 duplication articles were removed. About 514 studies were passed for screening by their titles and abstracts. About 449 articles were excluded based on their title and abstract review. In this systematic review and meta-analysis articles were screened using their title, abstract, and keywords of the studies. A total of 65 articles reported were sought for retrieval. Among the 65 articles, 42 articles reported were excluded because of the eligibility criteria. The screening of studies and search results

were supported by review matrix notes. A total of 23 articles report were underwent full data extraction. Ten studies were excluded due to different reasons as it indicated in PRISMA flow chart (Figure 1). Finally, in this systematic review and meta-analysis, a total of 13 cross-sectional studies were included with a total sample size or population of 3511 study participants (Table 1).

# 3.2 | Prevalence of obstructive lung patterns in Ethiopia

In this systematic review and meta-analysis the prevalence of percentage of FEV<sub>1</sub>/FVC ratio<70% cases, FEV<sub>1</sub> value <80% (percentage predicted values) was observed. The lowest prevalence (3.5%) of obstructive lung patterns was reported in the study conducted in Addis Ababa and Butajira<sup>11</sup> and the higher prevalence (24.2%) of obstructive lung patterns was observed in Addis Ababa.<sup>2</sup> Eight studies were included for the estimation of the pooled prevalence of obstructive lung patterns in Ethiopia. The pooled prevalence of obstructive lung patterns in occupational exposure at different workplaces in Ethiopia was found 13.04% (95% CI: 7.96, 18.12,  $I^2 = 89.2\%$ ) (Figure 2).

Percentage of FEV<sub>1</sub>/FVC ratio <70% controls, FEV<sub>1</sub> value <80% (percentage predicted values) was calculated. The lower prevalence (1%) was observed in the study conducted in Oromia, Addis Ababa, SNNP,<sup>22</sup> and the higher prevalence (10.8%) were studied in wolkite.<sup>9</sup> The pooled prevalence of obstructive lung patterns in controls was 4.10% (95% CI: 1.86, 6.34,  $I^2 = 76.8\%$ ) (Figure 3).

# 3.3 | Actual spirometric results at different workplaces in Ethiopia

The original data of spirometric measurement at different work sites were included in this systematic review and meta-analysis. All the FVC maneuver parameters were studied separately using spirometric interpretation.

# 3.3.1 | SMD of FVC (L) of the lung in cases and controls

FVC: the maximum amount of air that can exhale following a maximal inspiration effort, measured in liters (L). The result was summarized by using random-effect analysis. The SMD of FVC at 95% CI was -0.50(-0.70,-0.30) in the case and controls, respectively. In (Figure 4) seven studies showed the FVC was reduced in cases as compared to the controls. 1,2,4,13,14,22,24 Four studies showed moderately reduced FVC results in cases as compared to the controls 9-11,23 and two studies showed there was no significant change in FVC value in cases as compared to the controls 12,25 (Figure 4).

Characteristics of research articles included in the systematic review and meta-analysis (N = 13). TABLE 1

|    |                                  |                              |                 |                               | Sample size | size    | Prevalence obstructive lung pattern                          | tive lung pattern   | SE   |         |                  |
|----|----------------------------------|------------------------------|-----------------|-------------------------------|-------------|---------|--|---|------|---------|------------------|
| °Z | Authors and publication years    | Study site                   | Study design    | Type of occupational exposure | Case        | Control | FEV <sub>1</sub> /FVC ratio<br><70% case, FEV1<br>value <80% | FEV <sub>1</sub> /FVC ratio<br><70% control,<br>FEV1 value <80% | Case | Control | Quality<br>score |
| П  | Abaya et al. <sup>22</sup>       | Oromia, Addis<br>Ababa, SNNP | Cross-sectional | Coffee processing factories   | 115         | 110     | 12.17  | 1.00  | 3.05 | 0.95    | 7 points         |
| 7  | Asgedom et al. <sup>12</sup>     | North and south<br>Ethiopia  | Cross-sectional | Particle board workers        | 74          | 73      | I  | 1   | 1    | 1       | 8 points         |
| က  | Demeke and Halie <sup>1</sup>    | Addis Ababa                  | Cross-sectional | Flour mill workers            | 54          | 54      | 11.10  | 3.70  | 4.25 | 2.57    | 8 points         |
| 4  | Fentie et al. <sup>4</sup>       | Jimma                        | Cross-sectional | Woodworkers                   | 70          | 70      | I  | 1   | ı    | ı       | 7 points         |
| 2  | Getahun and Haile <sup>2</sup>   | Addis Ababa                  | Cross-sectional | Cleaners                      | 70          | 70      | 24.20  | 8.60  | 5.12 | 3.35    | 8 points         |
| 9  | Girma and Kebede <sup>13</sup>   | Addis Ababa                  | Cross-sectional | Steel workers                 | 35          | 40      | I  | 1   | ı    | ı       | 6 points         |
| 7  | Hassen and Ibrahim <sup>23</sup> | Jimma                        | Cross-sectional | Cobblestone paving workers    | 127         | 194     | I  | 1   | I    | I       | 6 points         |
| ∞  | Tesfaye et al. <sup>24</sup>     | Arba Minch                   | Cross-sectional | Textile factory workers       | 51          | 51      | 21.56  | 3.90  | 5.76 | 2.71    | 7 points         |
| 6  | Lagiso et al. <sup>14</sup>      | Hawassa                      | Cross-sectional | Flour mill factory<br>workers | 196         | 210     | I  | 1   | 1    | I       | 8 points         |
| 10 | Tamire et al. <sup>11</sup>      | Addis Ababa and<br>Butajira  | Cross-sectional | House fuel use                | 266         | 279     | 3.50   | 1.70  | 1.13 | 0.77    | 6 points         |
| 11 | Negatu et al. <sup>10</sup>      | Awash                        | Cross-sectional | Commercial farming workers    | 206         | 180     | 18.40  | 5.00  | 2.70 | 1.16    | 8 points         |
| 12 | Woldeamanuel et al.              | Wolkite                      | Cross-sectional | Agricultural workers          | 288         | 288     | 15.6   | 10.80   | 2.14 | 1.83    | 8 points         |
| 13 | Tefara Zele et al. <sup>25</sup> | Northwest                    | Cross-sectional | Textile factory workers       | 239         | 101     | 5.40   | 2.00  | 1.46 | 1.19    | 7 points         |
| ;  |                                  |                              |                 |                               |             |         |  |   |      |         |                  |

Abbreviations: FEV1, forced expiratory volume in one second; FEV1/FVC, percentage of the FVC; FVC, forced vital capacity; SE, Standard error of prevalence; SNNP, South nation nationality and people.

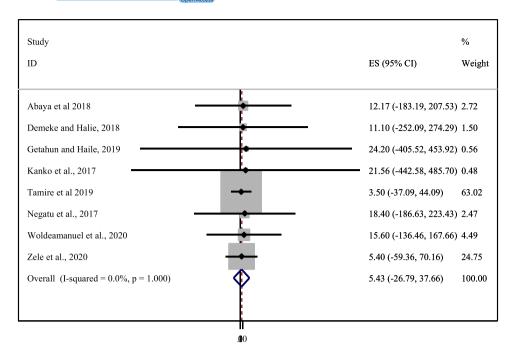


FIGURE 2 Percentage of FEV<sub>1</sub>/FVC ratio <0.7 cases, FEV1 value <80% (percentage predicted values).

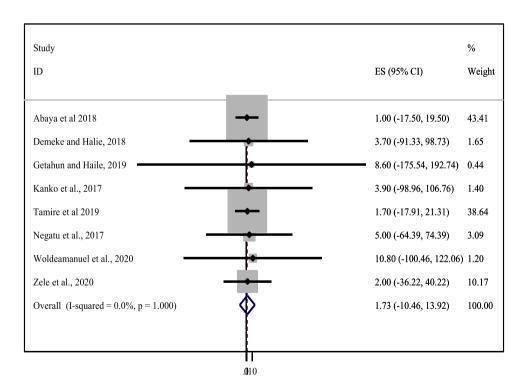


FIGURE 3 Percentage of FEV1/FVC ratio <0.7 Controls, FEV1 value <80% (percentage predicted values).

# 3.3.2 | SMD of $FEV_1$ (L) of the lung in cases and controls

Forced expiratory volume at one second ( $FEV_1$ ): The Volume of air exhaled in the first second during an FVC effort was also measured in a

litter (L), the SMD of FEV $_1$  at 95% CI was -0.54(-0.72,-0.36) in seven studies the FEV $_1$  showed a decreased FEV1 in cases as compared to the controls. <sup>1,2,4,13,14,22,24</sup> The SMD of FEV $_1$  of four studies <sup>9-11,25</sup> showed a decreased FEV $_1$  in cases as compared to controls, and two studies did not show a significant change in cases and controls <sup>12,23</sup> (Figure 5).

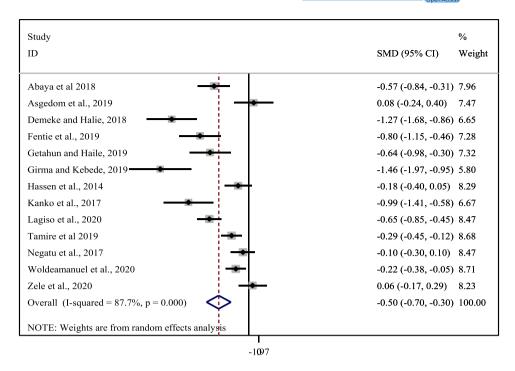


FIGURE 4 SMD of FVC (L) of cases and controls. FVC forced vital capacity; SMD, standardized mean differences.

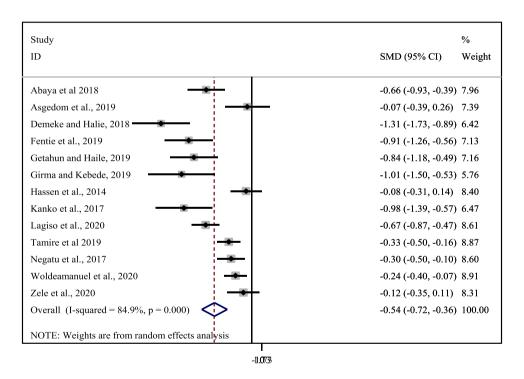


FIGURE 5 SMD of FEV<sub>1</sub> (L) of the lung in cases and controls. SMD, standard mean difference.

# 3.3.3 | SMD of FEF<sub>25</sub>%- $_{75}$ % (L/s) between cases and controls

The  $FEF_{25}\%_{-75}\%$  (mid expiratory flow) indicates expiratory flow in the middle portion of the FVC and the function of the medium and

smaller airways (L/s). The SMD of  $FEF_{25}\%_{-75}\%$  at 95% CI was -0.42 (-0.67,-0.17) and this shows a reduction of airway dimension in cases as compared to the controls. <sup>1,2,4,10,12,24</sup> One study shows there is insignificant change in cases as compared to the controls (Figure 6).

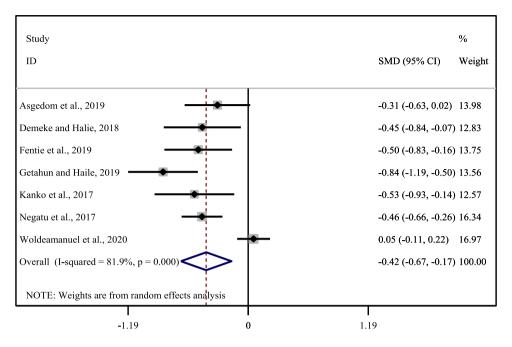


FIGURE 6 SMD of FEF<sub>25</sub>%-<sub>75</sub>% (L/s) between cases and controls. SMD, standard mean difference.

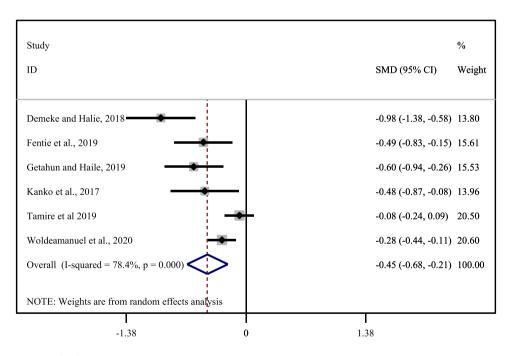


FIGURE 7 SMD of PEFR (L/s) between cases and controls. SMD, standard mean difference.

# 3.3.4 | SMD of peak expiratory flow rate (PEFR) (L/s) between cases and controls

PEFR: The highest flow achieved from maximal lung inflation and forced expiration, measured in the first 6–10 ms of a forced expiration which is measured in (L/s), assesses the function of larger airways. The SMD of PEFR at 95% CI was -0.45(-0.68,-0.21). The resistance of airway dimension due to dust exposure decrease the function of larger airways in cases as compared to the controls 1.2.4.9.11.24 (Figure 7).

### 3.4 | Influence analysis and heterogeneity

### 3.4.1 | Sensitivity analysis

Influence analysis of FEV $_1$ /FVC ratio <70% cases, FEV $_1$  value <80% (percentage predicted values) was done to assess the stability of the results (Supporting Information: File S2). There is an individual study that excessively influences the pooled prevalence of obstructive lung patterns.

**TABLE 2** Eggers test checking publication bias.

| Standard_Eff | Coef. | Standard Error | T     | p> t  | [95% CI]   |
|--------------|-------|----------------|-------|-------|------------|
| Slope        | -0.69 | 2.73           | -0.25 | 0.808 | -7.38,5.99 |
| Bias         | 4.79  | 1.31           | 3.65  | 0.011 | 1.57,7.99  |

### 3.4.2 | Publication bias

The FEV<sub>1</sub>/FVC ratio <70% cases, FEV<sub>1</sub> value <80% (percentage predicted values) was analyzed among the included eight studies, as seen by asymmetrical distribution of scatter plot (Supporting Information: File S3). The eggers test analysis showed there was a presence of publication bias statistically significant (p < 0.011) (Table 2).

### 3.4.3 | Subgroup analysis

Subgroup analysis was conducted in regard to the study regions and sexes ( $I^2$  = 89.2%, p = 0.000). Subgroup analysis was used to find the cause of heterogeneity across included studies of FEV<sub>1</sub>/FVC ratio <70%, and FEV<sub>1</sub> < 80% percentage predicted values. Based on the subgroup analysis, the pooled prevalence of FEV<sub>1</sub>/FVC ratio <70%, and FEV<sub>1</sub> < 80% percentage predicted values ranged from 11.13% in Oromia to 16.32% in SNNP. The SNNP region had the highest pooled prevalence of obstructive lung patterns followed by Addis Ababa with 12.71% (Supporting Information: File S4).

# 4 | DISCUSSION

The present review reported the pooled prevalence of obstructive lung patterns were considered as 13.04% and 4.10% in cases and controls respectively. In this study, the higher prevalence of obstructive lung patterns in cases may be attributed to prolonged exposure of occupational dusts, chemicals, unhygienic environment, and unsafe workplace as compared to the controls.

In North-East England study conducted by Melville and his Colleagues, the prevalence of spirometrically defined obstructive lung disease was 10% due to prolonged exposure to dust in unsafe workplaces. Similar findings were reported, studies conducted in global and regional estimates of COPD prevalence in 227 and 384 million affected cases were 10.7% (7.3%–14.0%) and 11.7% (8.4%–15.0%), respectively.<sup>26</sup> The study conducted in China also reports the prevalence of obstructive lung disease was 13.6% which supports our findings to seek wonderful preventable intervention approaches in dust–generating workplaces.

Based on the  $FEV_1/FVC$  ratio, the prevalence of obstructive lung patterns were investigated with occupational dust and chemical exposures. The prevalence of obstructive lung patterns in Ethiopia which accounts 13.04% was higher than the study conducted in

South afirica (5%) and in Iran (8.3%) but lower than the findings in Zimbabwe(27.8%), Russia(21.8%), and USA(19.2%). $^{27-31}$ 

The present study also investigated the actual spirometry results in different type of occupational exposures. The spirometric result was significantly reduced in exposed groups as compared to their matched controls. SMD of FVC, SMD of FEV<sub>1</sub>, SMD of FEF<sub>25</sub>%– $_{75}$ %, and SMD of PEFR were significantly reduced in cases as compared to controls.  $^{1,2,9,20,24,32,33}$  This may be due to the type of dust exposure that associated with the reduction of lung function like FEV<sub>1</sub>, FVC, and FEV<sub>1</sub>/FVC values.  $^{4,10,12,13}$  The study finding in Pakistan and Sweden showed as there is significant reduction in mean values of FEV<sub>1</sub> and FVC which further corroborate our findings.  $^{16,32,34}$ 

The percentage of FVC (FEV $_1$ /FVC ratio <70%) determines airflow obstruction $^{20}$  which reduces dynamic airway diameter that causes resistive work of breathing. The airway obstruction may cause pathophysiologic changes in the lungs $^6$  leading to airflow limitations. The airflow limitation may be due to mucus hypersecretion and ciliary dysfunction causing chronic cough and sputum production that affects the airway tract and makes it difficult for expiration.

The FEV<sub>1</sub>/FVC < 70% and FEV<sub>1</sub> < 80% predicted values were considered as obstructive lung patterns.  $^{1,2,6,9,15,17,19,20}$  The airflow limitation or obstruction patterns that happen in COPD are caused by the mixture of small airway disease, parenchymal destruction, and increased airway responsiveness. The SMD value of FEF<sub>25</sub>%- $_{75}$ % determines the function of smaller airways (L/s) that declined in cases compared to their matched controls. The SMD of PEFR persistently decreases in cases as compared to controls and represents collapsing of larger airways. This kind of airflow problem needs appropriate preventive measures for people who are working in different dust–generating environments.  $^{1,9,31,35}$ 

### 5 | STRENGTH AND LIMITATION

The study uses all experimental results to explore lung function by spirometry in different workplaces. This is the strength of the study. The limitation of this study may be the presence of high heterogeneity and publication bias. Additionally, inclusion of less or 13 cross-sectional studies and unable to include gray literature in this review decrease the evidence generated in this study.

# 6 | CONCLUSION

In this study, the pooled prevalence of obstructive lung patterns was higher in people who are working in different workplace that generating dusts and chemicals as compared to the controls. In addition our finding concludes, the SMD of the actual spirometric results were reduced in cases as compared to controls. Therefore, to alleviate obstructive lung patterns and to maintain lung spirometric result appropriate preventive measures should be warranted for those people who are working in different workplaces that generating dusts and chemicals.

#### Open Access

### **AUTHOR CONTRIBUTIONS**

**Dessalegn Demeke:** Conceptualization; data curation; investigation; methodology; validation; visualization; writing—original draft; writing—review & editing. **Endalamaw Tesfa:** Data curation; formal analysis; software; supervision; visualization; writing—review & editing.

### CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

#### DATA AVAILABILITY STATEMENT

All data used in this study are available in this document and its supporting information files.

### TRANSPARENCY STATEMENT

The lead author Dessalegn Demeke affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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### SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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