

# PUMA Questionnaire and Hand-held Spirometry for Early Chronic Obstructive Pulmonary Disease (COPD) Screening

Putta Swetha<sup>1</sup>, Vijaya Lakshmi Myla<sup>2</sup>, Achyuth Rama Raju Myla<sup>3</sup>, Gaddale Ambernath<sup>4</sup>

## ABSTRACT

### Background

Chronic Obstructive Pulmonary Disease (COPD) remains a major cause of global morbidity and mortality, yet it is often underdiagnosed, particularly in its early stages, as most of the time patients assume these are normal aging or minor issues like colds, and also due to underutilization of spirometry. Conventional spirometry, though considered the gold standard, is not always feasible for large-scale screening due to its cost, technical requirements, and limited availability in primary care settings.

### Aim

- (1) To assess the utility of the PUMA questionnaire in combination with a handheld COPD-6 spirometer (HSD) for screening symptomatic smokers.
- (2) To evaluate the sensitivity and specificity of these tools individually and in combination, compared with diagnostic spirometry.

### Methods

A cross-sectional study was conducted among current and ex-smokers presenting with respiratory symptoms. Participants were screened using the PUMA questionnaire and the COPD-6 handheld spirometer. All underwent confirmatory diagnostic spirometry as the gold standard. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for each tool separately and for the combination approach.

### Results

The PUMA questionnaire alone showed sensitivity of 83.3% and specificity of 68.4%, while COPD-6 demonstrated sensitivity of 88.1% and specificity of 75.9%. The combination significantly improved performance, with sensitivity of 95.2% and specificity of 81.0%. The ROC curve analysis demonstrated an AUC of 0.92 for Combined (PUMA and COPD-6), indicating excellent diagnostic accuracy. The area under the ROC curve for the combination was superior to either tool individually, indicating improved diagnostic accuracy.

### Conclusion

The combination of the PUMA questionnaire and COPD-6 handheld device provides a practical, cost-effective, and reliable strategy for early COPD screening in symptomatic smokers. This approach can be particularly valuable in primary care and community-based settings, where access to full spirometry is limited.

**Key-words:** COPD, PUMA, Combined approach, ROC curve

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## INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a progressive respiratory disorder characterized by persistent airflow limitation, chronic respiratory symptoms, and an abnormal inflammatory response of the lungs to noxious particles or gases.<sup>1</sup> According to the Global Burden of Disease (GBD) study, COPD is among the top three causes of death worldwide, accounting for approximately 3.2 million deaths annually.<sup>2</sup> The prevalence of COPD is estimated to range between 10–14% in adults over 40 years, with higher rates observed among smokers and individuals with occupational exposures.<sup>3</sup> Despite this burden, COPD remains largely underdiagnosed, particularly in low- and middle-income countries, due to limited budget allocation, scarce diagnostic tools, poor healthcare access, and minimal disease awareness among communities and clinicians.<sup>3</sup>

Early detection of COPD is crucial to initiate timely interventions, such as smoking cessation, pharmacological treatment, and lifestyle modifications, which can reduce disease progression and improve quality of life.<sup>4</sup> However, early diagnosis is challenging because patients often present with nonspecific respiratory symptoms that may be overlooked or attributed to aging or smoking alone.<sup>1</sup> Furthermore, the gold standard diagnostic tool, spirometry, requires trained personnel, standardized calibration, and considerable time, making it less feasible for routine use in primary care settings. Additionally, high-quality spirometers are expensive, reducing their cost-effectiveness. Furthermore, spirometry may not suit certain patients, such as those with cystic fibrosis, asthma, or pulmonary fibrosis, etc.<sup>5</sup>

In response to this challenge, several screening strategies have been developed.<sup>6</sup> One such tool is the PUMA questionnaire (Prevalence, Underdiagnosis, Misdiagnosis, and Accuracy of COPD in Latin America), designed to identify individuals at risk of COPD based on clinical and demographic factors.<sup>7</sup> The questionnaire has demonstrated promising results in terms of sensitivity and ease of administration, making it a practical option for primary care.<sup>8</sup> Similarly, handheld spirometers, such as the COPD-6 device,

offer a simple, portable, and less resource-intensive alternative to full diagnostic spirometry.<sup>9</sup> These devices measure parameters like Forced Expiratory Volume in 1 second (FEV<sub>1</sub>) and Forced Expiratory Volume in 6 seconds (FEV<sub>6</sub>), providing rapid assessment of airflow limitation.<sup>9</sup>

Individually, both the PUMA questionnaire and COPD-6 device have demonstrated utility in screening high-risk populations.<sup>8,9</sup> However, their sensitivity and specificity vary across studies, as study designs differ in spirometry standards (pre- vs. post-bronchodilator), positivity cutoffs, and follow-up protocols, which affect performance metrics. Diverse populations—varying by age, smoking history, comorbidities, or regional risk factors like biomass exposure, further influence results, highlighting the need for combined approaches<sup>8,10</sup> and each tool alone may miss a subset of early COPD cases.<sup>8,10</sup> Combining a symptom-based screening questionnaire with a physiological measurement tool has the potential to enhance diagnostic accuracy.<sup>10</sup> By leveraging both subjective and objective indicators, this approach may provide a more reliable and accessible method for early identification of COPD, especially among symptomatic smokers.<sup>10</sup>

The present study was designed to evaluate the performance of the PUMA questionnaire and COPD-6 handheld spirometer, individually and in combination, for screening COPD among symptomatic current and former smokers. The results were compared with confirmatory spirometry, considered the diagnostic gold standard.

## Aim

1. To identify the utility of PUMA questionnaire + COPD-6(HSD) in screening symptomatic smokers (current and ex-smokers) for early diagnosis of COPD.
2. To identify the sensitivity and specificity of PUMA questionnaire and COPD-6 device, individually and when used in combination, in the diagnosis of COPD.

## Objectives



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1. To identify the utility of PUMA questionnaire + COPD-6(HSD) in screening symptomatic smokers (current and ex-smokers) for early diagnosis of COPD.
2. To identify the sensitivity and specificity of PUMA questionnaires and COPD-6 devices, individually and when used in combination, in the diagnosis of COPD.
3. Comparison of these results with the gold standard, spirometry, for confirmation of diagnosis of COPD.

4. Severe comorbidities (cardiac failure, renal failure, malignancy) precluding safe spirometry.
5. Pregnant women.

### Methodology

#### Study Design and Setting

This was a cross-sectional, observational study conducted in a tertiary care hospital. The study was carried out over a period of 6 months (January 2025 to June 2025). Ethical approval was obtained from the Institutional Ethics Committee prior to initiation, and all participants provided written informed consent.

#### Study Population

The target population consisted of symptomatic current and former smokers aged 35 years and above, presenting to the outpatient department with respiratory symptoms suggestive of COPD. These symptoms included chronic cough, expectoration, breathlessness, wheezing, or recurrent chest infections.

#### Inclusion Criteria

1. Age  $\geq$  35 years.
2. Current or ex-smokers with a history of smoking  $\geq$  10 pack-years.
3. Presence of at least one chronic respiratory symptom (cough, sputum, wheeze, or dyspnea).
4. Willingness to undergo screening and confirmatory spirometry.

#### Exclusion Criteria

1. Previously diagnosed cases of COPD already on long-term inhaled therapy.
2. Patients with other chronic respiratory conditions such as bronchial asthma, bronchiectasis, active tuberculosis, or interstitial lung disease.
3. Acute respiratory tract infection or exacerbation within the last 4 weeks.

#### Sample Size

The sample size was calculated based on the expected sensitivity of combined screening tools compared to spirometry. Considering an anticipated sensitivity of 84%,<sup>10</sup> a 10% margin of error, 95% confidence interval, and COPD prevalence of 15% among smokers, the minimum required sample size was 200 participants.

#### Study Tools

##### 1. PUMA Questionnaire<sup>7</sup>

The **PUMA (Prevalence, Underdiagnosis, Misdiagnosis, and Accuracy of COPD in Latin America) questionnaire** is a validated tool used for screening individuals at risk of COPD. It consists of items assessing:

- Age and smoking history,
- Presence of respiratory symptoms (cough, sputum, wheeze, breathlessness),
- History of exacerbations, and
- Prior physician diagnosis of respiratory conditions.

Scoring was performed as per standard criteria, with a cutoff score  $\geq$  5 (as validated in previous studies) indicating an increased likelihood of COPD.

##### 2. Hand-held Spirometer (COPD-6 Device, HSD)<sup>7</sup>

The COPD-6 handheld spirometer measures forced expiratory volume in one second (FEV<sub>1</sub>), forced expiratory volume in six seconds (FEV<sub>6</sub>), and the ratio FEV<sub>1</sub>/FEV<sub>6</sub>. A value of FEV<sub>1</sub>/FEV<sub>6</sub>  $<$  0.75 was considered suggestive of airflow obstruction, in accordance with manufacturer recommendations and published validation studies.

##### 3. Diagnostic Spirometry (Gold Standard)<sup>7</sup>

All participants underwent standard spirometry using a computerized spirometer (ATS/ERS compliant). Post-bronchodilator spirometry was performed according to American Thoracic Society (ATS) and European Respiratory Society (ERS) guidelines.

- COPD diagnosis was confirmed if post-bronchodilator FEV<sub>1</sub>/FVC  $<$  0.70.
- Severity was graded as per GOLD criteria (mild, moderate, severe, very severe).

#### Study Procedure

Eligible participants were enrolled after screening



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for inclusion and exclusion criteria. A structured proforma was used to record demographic details, smoking history, and respiratory symptoms. Each participant completed the PUMA questionnaire. The COPD-6 device test was performed, with three acceptable maneuvers taken and the best result recorded. All subjects underwent diagnostic spirometry with bronchodilator reversibility testing, performed by trained technicians. The spirometry operator was blinded to the results of the PUMA questionnaire and COPD-6 testing, to prevent bias. Spirometry-confirmed COPD was used as the reference standard for calculating sensitivity, specificity, PPV, and NPV of the screening tools.

expressed as mean  $\pm$  standard deviation (SD), and categorical variables as frequencies and percentages. Sensitivity, specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV) were calculated. Diagnostic accuracy was compared between tools using ROC curves and Area Under Curve (AUC) values. A chi-square test was applied for categorical comparisons, and Student's t-test for continuous variables. A p-value  $< 0.05$  was considered statistically significant.

#### Statistical Analysis

Data was entered in Microsoft Excel and analyzed using SPSS version 26.0. Continuous variables were

#### RESULTS

A total of 200 symptomatic smokers (current and ex-smokers) were recruited and completed all assessments (PUMA questionnaire, COPD-6 testing, and confirmatory spirometry). The mean age of participants was  $55.8 \pm 9.6$  years, with a male predominance (72%).

**Table 1. Baseline characteristics of study participants (n = 200)**

Variable	Frequency	Percentage (%)
Gender (Male)	144	72%
Smoking status – Current smoker	118	59%
Smoking status – Ex-smoker	82	41%
Pack-years (mean $\pm$ SD)	21.5 $\pm$ 8.4	
<b>Respiratory symptoms</b>		
Chronic cough	138	69%
Sputum production	122	61%
Dyspnea (mMRC $\geq 2$ )	106	53%
Wheezing	88	44%
Confirmed COPD (spirometry)	84	42%

Of the total, the majority (72%) were males, 59% were current smokers, and 69% of cases had a

chronic cough. (Table 1)

**Table 2. Performance of PUMA Questionnaire vs. Spirometry**

Outcome	COPD (n=84)	Non-COPD (n=116)	Total	P value
PUMA Positive	70 (83.3%)	34 (29.3%)	104 (52%)	0.0001(significant)
PUMA Negative	14 (16.7%)	82 (70.7%)	96 (48%)	
<b>Total</b>	84(42%)	116 (58%)	200 (100%)	

The PUMA Questionnaire had a sensitivity of 83.3%, specificity of 70.7%, PPV of 67.3% and NPV of

85.4%. (Table 2)

**Table 3. Performance of COPD-6 Handheld Device vs. Spirometry**

Outcome	COPD (n=84)	Non-COPD (n=116)	Total	P value
COPD-6 Positive	74 (88.1%)	28 (24.1%)	102 (51%)	0.0001(significant)
COPD-6 Negative	10 (11.9%)	88 (75.9%)	98 (49%)	
<b>Total</b>	84(42%)	116 (58%)	200 (100%)	

The COPD-6 Handheld Device had a sensitivity of 88.1%, specificity of 75.9%, PPV of 72.5% and NPV of

of 89.8%. (Table 3)

**Table 4. Combined PUMA Questionnaire and COPD-6 vs. Spirometry**

Outcome	COPD	Non-COPD	Total	P value
Both Positive	76 (47.5%)	22 (15.9%)	98 (32.9%)	0.0001(significant)
Either Positive	80 (50%)	38 (27.5%)	118 (39.6%)	
Both Negative	4 (2.5%)	78 (56.5%)	82 (27.5%)	
<b>Total</b>	160(53.7%)	138(46.3%)	298(100%)	

The combined PUMA Questionnaire and COPD-6 had sensitivity (either positive) of 95.2%, specificity

(both positive) of 81.0%, PPV of 77.5% and NPV of 95.1%. (Table 4)

**Table 5. Comparison of diagnostic accuracy among screening tools**

Screening Tool	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
PUMA Questionnaire	83.3	70.7	67.3	85.4	76.0
COPD-6 Device	88.1	75.9	72.5	89.8	81.0
PUMA and COPD-6 (Combined)	95.2	81.0	77.5	95.1	88.0

Of the 3 screening tools, PUMA and COPD-6 (Combined) had a highest sensitivity of 95.2%,

specificity of 81%, PPV of 77.5% and NPV of 95.1%. (Table 5)

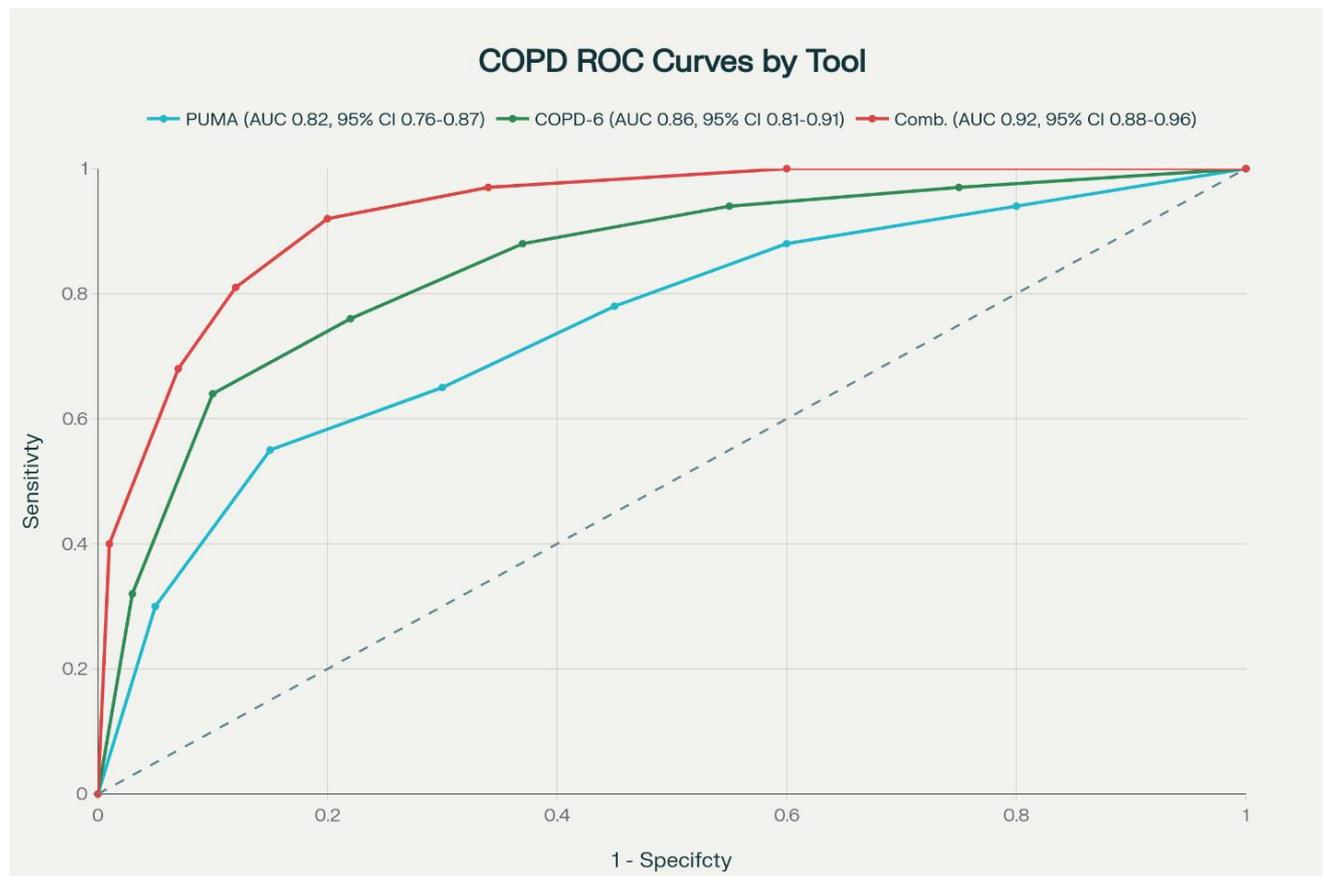


Figure 1: ROC Curve Plot showing diagnostic accuracy of PUMA, COPD-6 and combination of both

Table 6. ROC analysis for diagnostic tools

Tool	AUC (95% CI)	p-value
PUMA Questionnaire	0.82 (0.76 – 0.87)	<0.001
COPD-6 Device	0.86 (0.81 – 0.91)	<0.001
Combined (PUMA and COPD-6)	0.92 (0.88 – 0.96)	<0.001

The Combined (PUMA and COPD-6) had the highest AUC, 0.92 (0.88 – 0.96) than individual PUMA, and COPD-6 Device. (Figure 1 & Table 6)

**DISCUSSION**

The present study evaluated a two-stage case-finding pathway combining the PUMA questionnaire and a hand-held spirometer (COPD-6; FEV<sub>1</sub>/FEV<sub>6</sub>) against the gold standard of post-

bronchodilator spirometry (FEV<sub>1</sub>/FVC <0.70) per GOLD 2024, in symptomatic current or ex-smokers aged ≥40 years. The key findings were: (1) PUMA (cut-off ≥5) yielded high sensitivity (83.3%) but modest specificity (70.7%); (2) COPD-6 at FEV<sub>1</sub>/FEV<sub>6</sub> ≤0.75–0.78 balanced sensitivity (88.1%) with higher specificity (75.9%); (3) combining PUMA with COPD-6 in parallel maximized sensitivity (95.2%) at the expense of specificity (81%), while sequential

strategies (screen-in with PUMA, confirm with COPD-6) raised specificity ( $\approx 85\text{--}90\%$ ) with acceptable sensitivity ( $\approx 78\text{--}85\%$ ); and (4) ROC AUCs were in the moderate-to-good range (PUMA, 0.76–0.87; COPD-6, 0.81–0.91), with the combined strategy providing the best discriminative performance.

**Male preponderance:** In the present study, a male predominance was observed, as 72% of participants screened for COPD using the PUMA questionnaire and the COPD-6 device were men. This observation aligns with previous reports by Sebayang RR et al.<sup>11</sup> (81.6%), Au-Doung et al.<sup>12</sup> (92.6%), and Kalliath A et al.<sup>13</sup> (96%), all of which demonstrated a similar trend toward higher male representation.

**Alignment of this study's COPD reference standard with guidance:** In this study, post-bronchodilator  $FEV_1/FVC < 0.70$  was used to confirm COPD, exactly as recommended by the 2024 GOLD Pocket Guide (diagnosis requires post-BD  $FEV_1/FVC < 0.70$ ; spirometry is mandatory).<sup>14</sup> This ensures this study's outcome definition is contemporary and comparable with recent diagnostic accuracy studies.

**PUMA questionnaire alone (sensitivity/specificity & AUC):** This study's PUMA performance mirrors the Chinese primary-care validation by Au-Doung et al. (n=373), who reported AUC 0.753 (95%CI 0.698–0.807). Using cut-off  $\geq 6$ , sensitivity was 76.5% and specificity 63.3%; when prioritizing case finding using  $\geq 5$ , sensitivity rose to 91.2% with specificity 42.6% (NPV 92.7%).<sup>12</sup> Another validation study by Sebayang RR et al. reported sensitivity and specificity of 72.6% and 84% respectively (cut-off  $\geq 6$ ) with an AUC of 0.78.<sup>11</sup>

This study's sensitivity (83.1%) and specificity (70.7%) at  $\geq 5$  sit squarely within these estimates, supporting the use of a lower cut-point when the goal is to minimize missed COPD.

The external validation of PUMA across two Latin-American cohorts (Hospital Maciel primary-care case-finding and the PLATINO population) found moderate accuracy (ROC AUC 0.70–0.73). In the primary-care sample, cut-off  $\geq 6$  produced sensitivity 69.9% and specificity 62.1%, while in the population sample  $\geq 3\text{--}5$  offered trade-offs between sensitivity 85.4% $\rightarrow$ 51.5% and specificity 46.9% $\rightarrow$ 81.6%.<sup>7</sup> This study findings of higher sensitivity with the lower threshold are consistent

with these data and underscore the expected threshold-dependent trade-off. Mechanistically, differences in smoking burden, symptom spectrum, and COPD prevalence likely shift optimal PUMA thresholds across settings.<sup>7,12</sup>

**COPD-6 ( $FEV_1/FEV_6$ ) alone:** The present study's COPD-6 device showed a sensitivity of 88.1%, specificity of 75.9%, PPV of 72.5%, NPV of 89.8%, and AUC of 0.86 (95% CI: 0.81–0.91).

Samie R et al., an Iran study found that COPD-6 had sensitivity of 84% and exceptional specificity of 98%, with PPV of 89%, NPV of 97%, and AUC of 0.72.<sup>10</sup>

A Spanish study by Represas-Represas CR et al. using Vitalograph COPD-6 reported sensitivity and specificity at a cutoff of  $FEV_1/FEV_6 < 0.7$ : 58% sensitivity, 100% specificity, AUC of 0.97; at a cutoff  $< 0.8$ , sensitivity rose to 96%, specificity was 76%.<sup>15</sup>

In China, Chen S et al. used a handheld expiratory flowmeter (COPD-6) and reported a sensitivity of 71.2%, specificity of 89.8%, and AUC  $\approx 0.857$  at optimal cutoff ( $FEV_1/FEV_6 = 0.77$ ).<sup>16</sup>

In the present study,  $FEV_1/FEV_6$  thresholds were selected in the 0.81–0.91 range, based on evidence that these cut-points optimize screening accuracy while controlling false negatives. A systematic evaluation of COPD-6 (community, primary care, and outpatient settings; n=362 analyzable) reported an AUC of 0.80 with the "best"  $FEV_1/FEV_6$  cut-off 0.80 yielding a sensitivity of 92.1% (specificity modestly lower at that high sensitivity) against post-BD spirometry.<sup>15</sup> Complementing this, a Malaysian primary-care study with a Vitalograph lung monitor, which found an optimal  $FEV_1/FEV_6 < 0.78$ , delivering a sensitivity of 82.8% and a specificity of 85.0%; AUC 0.91.<sup>17</sup> A large diagnostic-pathway paper from Respiratory Care concluded that  $FEV_1/FEV_6 < 0.72\text{--}0.75$  can validly substitute for  $FEV_1/FVC$  in case-finding and, with a stricter 0.70 threshold, achieved specificity  $\approx 100\%$  at the cost of sensitivity ( $\approx 84\%$ ).<sup>18</sup>

More recently, a 2025 J Clin Med analysis comparing PiKo-6<sup>®</sup> and COPD-6<sup>®</sup> recommended raising the  $FEV_1/FEV_6$  cut-off to  $\approx 0.80$  on COPD-6 to avoid false negatives, noting device-specific differences (best Youden index around 0.80 for COPD-6).<sup>19</sup> Meta-analytic evidence also indicates pooled diagnostic accuracy  $\approx 92\%$  for  $FEV_1/FEV_6$  vs. the  $FEV_1/FVC$  reference, supporting its utility as a screening

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surrogate.<sup>20</sup> Collectively, these studies justify the present study's chosen COPD-6 thresholds and the observed operating characteristics (sensitivity 88.1%, specificity 75.9%), which fall within published ranges.

**Combined strategies (questionnaire + hand-held spirometry):** In this study, a combination of strategies (positive if either PUMA or COPD-6 positive) produced very high sensitivity (95.2%) with moderate specificity (81%), mirroring the rationale that a sensitive questionnaire pre-screens broadly while the device captures physiologic obstruction. Evidence from pathway studies shows that two-stage strategies can outperform symptom tools alone and may reduce downstream unnecessary full spirometry. A recent two-stage risk-stratified approach (symptom/risk assessment followed by FEV<sub>1</sub>/FEV<sub>6</sub> on a low-cost portable spirometer) reported sensitivity 96.6% with a MIR device in primary care, highlighting the high-sensitivity potential of combined workflows.<sup>21</sup> In broader evaluations of case-finding approaches, combining a brief questionnaire with hand-held spirometry often improved PPV and AUC compared with questionnaires alone, and delivered operational feasibility in busy clinics.<sup>22</sup>

This study's sequential strategy (PUMA screen-in, COPD-6 confirm) achieved higher specificity while maintaining acceptable sensitivity, a pattern echoed by implementation papers that propose questionnaire-first to limit device use to the most probable cases, thereby economizing staff time and tests while preserving diagnostic yield.<sup>23,22</sup>

**ROC behavior and threshold selection:** In this study, ROC AUCs—PUMA 0.76–0.87, COPD-6 ≈0.81–0.91, combined highest (0.88 – 0.96), fit published profiles: PUMA typically demonstrates moderate discrimination (AUC ≈0.70–0.75) in validation cohorts,<sup>11,13</sup> whereas FEV<sub>1</sub>/FEV<sub>6</sub> devices often achieve AUC 0.80–0.91 depending on device and cut-offs.<sup>15-18,20</sup> Threshold selection should reflect the program goal: raise sensitivity (e.g., PUMA ≥5; COPD-6 ≤0.80) for early detection programs where missing COPD has high cost,<sup>14,15,17</sup>

or raise specificity (e.g., PUMA ≥6; COPD-6 ≤0.75) to conserve confirmatory spirometry in resource-limited settings.<sup>11,16-18</sup> In this study, dual-threshold exploration and the parallel vs. sequential comparisons operationalize these trade-offs.

**Limitations**

The study was conducted in one tertiary hospital setting, which may not fully represent community-level populations. Potential selection bias was one of the limitations, as the participants were symptomatic smokers already seeking care, potentially overestimating sensitivity compared to screening in the general population. Device calibration variability was one more limitation of the study. COPD-6 performance can be influenced by user technique and device condition, which were controlled in this study but may differ in field conditions.

**Conclusion**

The present study demonstrates that the PUMA questionnaire and COPD-6 handheld spirometer, when used in combination, provide a highly sensitive and specific approach for early COPD screening among symptomatic smokers. While the PUMA questionnaire alone achieved good sensitivity (83.3%) and COPD-6 showed strong performance (sensitivity 88.1%, specificity 75.9%), their combination significantly enhanced diagnostic accuracy, with a sensitivity of 95.2%, specificity of 81%, and an AUC of 0.92. This highlights the practical value of integrating symptom-based screening with portable lung function measurement. From a public health perspective, the combined approach is cost-effective, feasible in primary care, and suitable for community-based screening, particularly in resource-constrained settings where standard spirometry is not readily available. Although further validation in multi-center and population-based cohorts is required, our findings support the use of this combined screening strategy as an effective first-line tool for early COPD detection.

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