

Evaluation of the effectiveness of om-85 bv combination therapy in chronic obstructive pulmonary disease at Bai Chay Hospital, 2024 – 2025

Pham Thi Ut Trang², Pham Van Thuc¹, Le Thi Dieu Hien^{1*}, Dao Hong Ngu²

ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is a major global health burden. Frequent exacerbations worsen lung function, quality of life, and healthcare costs. OM-85 BV (Broncho-Vaxom) is an oral immunomodulator derived from bacterial lysates, investigated for reducing respiratory infections and COPD exacerbations. **Objective:** To evaluate the clinical effectiveness of OM-85 BV in COPD patients at Bai Chay Hospital. **Methods:** A descriptive case-series study combining retrospective and prospective data was conducted in 119 outpatients with COPD (GOLD stage B or higher, ≥ 40 years old) between 2024 and 2025. Patients received standard COPD therapy plus OM-85 BV. Clinical data, exacerbations, antibiotic and corticosteroid use, and lung function (FEV₁) were analyzed using SPSS 22.0. **Results:** OM-85 BV significantly reduced exacerbations, antibiotic and corticosteroid use, and improved lung function. **Conclusion:** OM-85 BV represents a promising adjunctive therapy for COPD management in Vietnam.

Keywords: COPD, OM-85 BV, Broncho-Vaxom, exacerbation, lung function

¹ Hai Phong University of Medicine and Pharmacy, Vietnam
² Bai Chay Hospital, Vietnam

* Corresponding author

Le Thi Dieu Hien
Email: ltdhien@hpmu.edu.vn

Received: June 09, 2025

Reviewed: June 11, 2025

Accepted: June 25, 2025

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a progressive respiratory disease characterized by persistent airflow limitation and chronic symptoms. Globally, more than 328 million people are affected, and COPD is projected to become a leading cause of death within 15 years. In Vietnam, COPD imposes a substantial public health and economic burden. OM-85 BV (Broncho-Vaxom) is an oral bacterial lysate with immunomodulatory properties. This study aimed to evaluate the clinical outcomes of OM-85 BV in COPD patients at Bai Chay Hospital.

METHODS

Study design

Descriptive case-series with retrospective and prospective data collection.

Population

119 COPD outpatients (GOLD stage B or higher) at Bai Chay Hospital (2024–2025).

Inclusion criteria: Age ≥ 40 years, diagnosis of COPD (GOLD 2024).

Exclusion criteria: Autoimmune diseases, malignancies, HIV, tuberculosis, OM-85 BV use within 12 months, or hypersensitivity to OM-85 BV.

Data analysis: SPSS 22.0. Continuous variables presented as mean \pm SD; categorical variables as percentages.

RESULTS

Table 1. Age distribution of study subjects

Age group	Frequency (N)	Percentage (%)
40 – 49	0	0.0
50 – 59	8	6.7
60 – 69	39	32.8
≥ 70	72	60.5
Total	119	100.0

Min–Max: 50–92 | Mean ± SD: 71.66 ± 8.20

Remark: The majority of patients were aged ≥70 years (60.5%), with a mean age of 71.66 ± 8.20 years, highlighting COPD as a disease predominantly affecting the elderly.

Table 2. Mean COPD exacerbations before and after OM-85 BV treatment

Mean COPD exacerbations before and after OM-85 BV treatment	$\bar{x} \pm SD$	p
3 months before (1)	0,86 ± 1,49	0,001
3 months after (2)	0,33 ± 1,26	
6 months before (3)	1,37 ± 1,40	0,001
6 months after (4)	0,50 ± 0,71	

Remark: Exacerbations significantly decreased after 3 months (from 0.86 ± 1.49 to 0.33 ± 1.26) and after 6 months (from 1.37 ± 1.40 to 0.50 ± 0.71). Statistical analysis using the Paired Samples T-test confirmed that these reductions were highly significant ($p < 0.001$), indicating a therapeutic benefit of OM-85 BV in reducing COPD exacerbation rates.

Table 3. Mean number of antibiotic days before and after OM-85 BV treatment

Mean number of antibiotic days before and after OM-85 BV treatment	Mean rank	n	χ^2 (df)	p
12 months before	4,22	119	215.378 (4)	< 0,001
6 months before	3,48			
3 months before	2,66			
3 months after	2,04			
6 months after	2,60			

Remark: The Friedman test revealed a statistically significant difference in the number of antibiotic use days across the five time points ($\chi^2(4) = 215.378$, $p < 0.001$). The mean ranks indicated a clear decreasing trend in antibiotic use over time, from the highest before 12 months (Mean Rank = 4.22) to the lowest after 3 months (Mean Rank = 2.04), suggesting that OM-85 BV therapy contributed to reducing the frequency of antibiotic use in patients with COPD.

Table 4. Mean number of systemic corticosteroid days before and after OM-85 BV treatment

Mean number of systemic corticosteroid days before and after OM-85 BV treatment	Mean rank	n	χ^2 (df)	p
---	-----------	---	---------------	---

12 months before	3,69	119	120,030 (4)	< 0,001
6 months before	3,36			
3 months before	2,95			
3 months after	2,44			
6 months after	2,66			

Remark: The Friedman test revealed a statistically significant difference in systemic corticosteroid use across the five time points ($\chi^2(4) = 120.030, p < 0.001$). Mean rank values showed a clear downward trend in corticosteroid use after OM-85 BV treatment, with the lowest rank observed at 3 months post-therapy, indicating a reduction and stabilization of systemic corticosteroid requirement over time.

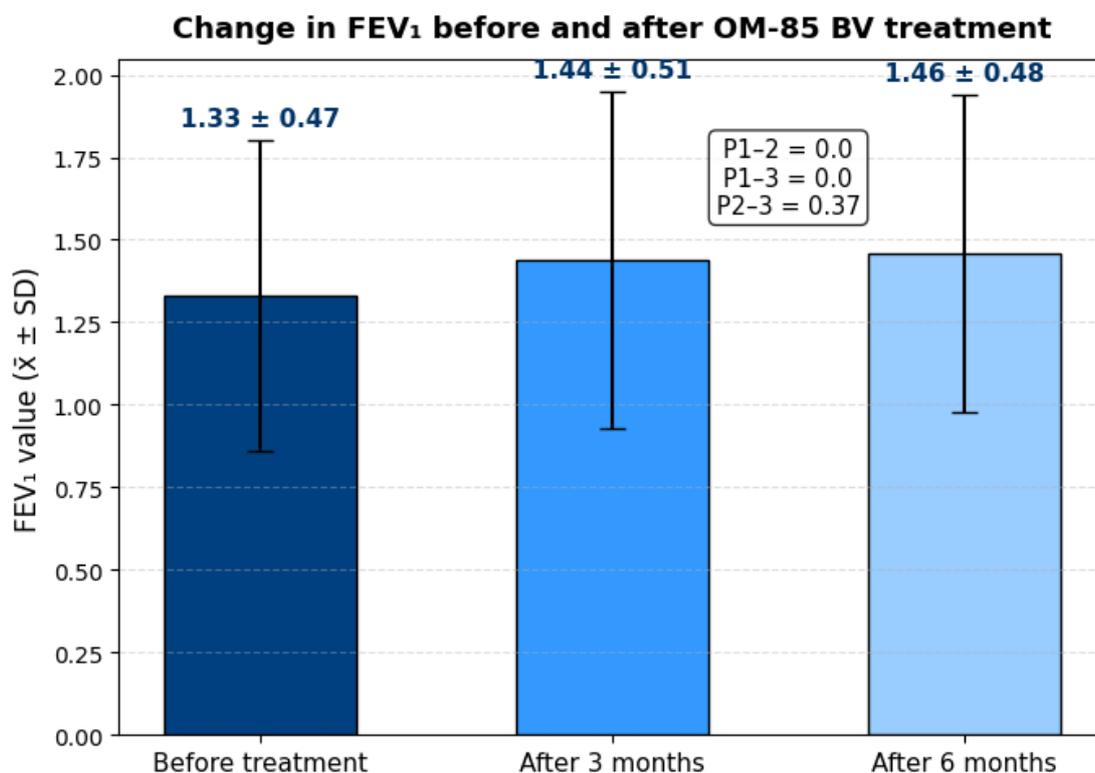


Figure 1. Changes in mean FEV1 before and after OM-85 BV treatment

Remark: Mean FEV1 improved significantly after OM-85 BV therapy at 3 and 6 months compared to baseline ($p < 0.001$).

DISCUSSION

In our study of 119 COPD patients, the mean age was 71.66 ± 8.20 years, with the majority being ≥ 70 years (60.5%). This finding is consistent with the study by Nguyen Duy Tung (2025), in which 61.9% of patients were older than 70 years, with a mean age of 72.35 ± 8.84 years [5]. Other studies have also demonstrated that COPD predominantly affects the elderly population.

For example, Vu Thanh Lich (2025) reported that 79.2% of COPD patients were aged ≥ 60 years, and the majority were male (98.0%) [6].

Regarding sex distribution, our study showed that males accounted for 66.4% and females for 33.6%. This result is consistent with previous research: Nguyen Quang Doi (2019) reported a male proportion of 91% [7]; Nguyen Duy Tung (2025) reported 85.1% male patients [5]; and Joon Young

Choi (2023) found that 79.8% of COPD patients were male [8]. These data reflect the general epidemiological pattern in which COPD is more common in men, largely due to the higher prevalence and earlier initiation of smoking among men. However, with smoking prevalence among women reaching approximately 28%, several studies have indicated that the health burden of COPD in women and even in never-smokers is increasing [9].

In our study, the addition of OM-85 BV to standard COPD therapy demonstrated clear benefits across multiple clinical outcomes. Prior to treatment, patients experienced relatively frequent exacerbations (0.86 ± 1.49 in the previous 3 months and 1.37 ± 1.40 in the previous 6 months). After 3 and 6 months of OM-85 BV therapy, the mean exacerbation frequency significantly declined to 0.33 ± 1.26 and 0.50 ± 0.71 , respectively ($p < 0.001$). In parallel, respiratory function improved substantially: mean FEV1 increased from 1.33 ± 0.47 L at baseline to 1.44 ± 0.51 L after 3 months and 1.46 ± 0.48 L after 6 months ($p < 0.001$). Distribution by severity showed an increase in the proportion of patients in the mild-to-moderate categories, while the proportion in severe and very severe groups decreased.

Patients' quality of life and respiratory symptoms also improved. Based on CAT (COPD Assessment Test) scores, the mean decreased from 15.34 ± 8.19 to 12.16 ± 7.10 after 3 months and 11.42 ± 7.06 after 6 months ($p < 0.001$). The proportion of patients with lower CAT scores nearly doubled, while the "very high" category disappeared entirely after 3 months and remained absent at 6 months. Furthermore, the proportion of patients without dyspnea increased from 15.1% before treatment to 39.5% after 3 months and 43.7% after 6

months. The mean mMRC (Modified Medical Research Council) dyspnea score significantly decreased from 1.57 ± 1.08 to 0.84 ± 0.93 after 6 months ($p < 0.001$), indicating that OM-85 BV contributed to improvements in dyspnea and daily functional capacity.

Importantly, the use of antibiotics and systemic corticosteroids decreased markedly following treatment. The mean number of antibiotic days showed a consistent downward trend across five time points, from the highest at 12 months before treatment (Mean Rank = 4.22) to the lowest at 3 months after therapy (Mean Rank = 2.04) ($\chi^2(4) = 215.378$, $p < 0.001$). Similarly, corticosteroid use decreased significantly, with mean rank declining from 3.69 (12 months before) to 2.44 (3 months after) ($\chi^2(4) = 120.030$, $p < 0.001$). This highlights that OM-85 BV not only reduces exacerbation frequency but also minimizes the need for systemic corticosteroid, which are associated with substantial adverse effects.

Our results are in line with findings from other international studies. Joon Young Choi (2023) demonstrated that OM-85 BV reduced the number of moderate-to-severe exacerbations and prolonged the time to next exacerbation [8]. Similarly, in a randomized controlled trial involving 273 patients with newly diagnosed COPD or chronic bronchitis, Solèr et al. (2006) reported a 29% reduction in exacerbation rate in the OM-85 BV group compared with placebo (0.61 vs. 0.86; $p = 0.03$) [10]. These findings strengthen the evidence for OM-85 BV as an effective strategy in preventing COPD exacerbations.

Collectively, current evidence suggests that OM-85 BV is a valuable immunomodulatory agent in COPD management. The GOLD 2023 executive

summary also cites studies supporting the role of OM-85 BV in reducing the frequency and severity of COPD exacerbations [11].

CONCLUSION

Adjunctive therapy with OM-85 BV in COPD patients at Bai Chay Hospital resulted in significant reductions in exacerbations, decreased antibiotic and systemic corticosteroid use, and improvements in lung function. OM-85 BV is a valuable adjunctive option in the long-term management of COPD in Vietnam.

Acknowledgements

The authors would like to thank Bai Chay Hospital and Hai Phong University of Medicine and Pharmacy for supporting this study.

Conflict of Interest

The authors declare no conflict of interest.

REFERENCES

1. Patel N. An update on COPD prevention, diagnosis, and management. *Nurse Pract.* 2024;49:29–36. doi:10.1097/01.NPR.0000000000000180.
2. Quaderi SA, Hurst JR. The unmet global burden of COPD. *Glob Health Epidemiol Genom.* 2018;3:e4. doi:10.1017/GHEG.2018.1.
3. Safiri S, Carson-Chahhoud K, et al. Burden of chronic obstructive pulmonary disease and its attributable risk factors in 204 countries and territories, 1990–2019: results from the Global Burden of Disease Study 2019. *BMJ.* 2022;378:e069679. doi:10.1136/BMJ-2021-069679.
4. Gareri P, Trevisan C. Efficacy of OM-85 in recurrent respiratory tract infections. *Rev Recent Clin Trials.* 2023;18(3).
5. Nguyen DT, Pham TM. Đặc điểm lâm sàng, cận lâm sàng của người bệnh COPD đợt cấp điều trị tại Bệnh viện Hữu nghị Việt Tiệp năm 2023. *Tạp chí Y học Việt Nam.* 549:13931. doi:10.51298/VMJ.V549I3.13931.
6. Vu TL, Tran VS, Dang DK. Đánh giá tính hợp lý trong sử dụng thuốc điều trị bệnh phổi tắc nghẽn mạn tính giai đoạn ổn định trên bệnh nhân ngoại trú. *Tạp chí Y Dược học Cần Thơ.* (87). doi:10.58490/ctump.2025i87.3825.
7. Nguyen QD. Nghiên cứu đặc điểm lâm sàng, cận lâm sàng và một số yếu tố nguy cơ tác động mạch phổi cấp ở bệnh nhân đợt cấp bệnh phổi tắc nghẽn mạn tính. *Luận án tiến sĩ Y học.* Hà Nội: Đại học Y Hà Nội.
8. Choi JY, Park YB, et al. Effect of Broncho-Vaxom (OM-85) on the frequency of chronic obstructive pulmonary disease exacerbations. *BMC Pulm Med.* 2023;23:1–8. doi:10.1186/s12890-023-02665-4.
9. Jenkins CR, Chapman KR, et al. Improving the management of COPD in women. *Chest.* 2017;151:686–96. doi:10.1016/j.chest.2016.10.031.
10. Soler M, Mütterlein R, Cozma G. Double-blind study of OM-85 in patients with chronic bronchitis or mild chronic obstructive pulmonary disease. *Respiration.* 2006;74:26–32. doi:10.1159/000093933.
11. Agustí A, Celli BR, et al. Global initiative for chronic obstructive lung disease 2023 report: GOLD executive summary. *Am J Respir Crit Care Med.* 2023;207:819–37. doi:10.1164/rccm.202301-0106PP.