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## COMPARING DRUG THERAPIES AND DIETARY INTERVENTIONS FOR COPD AND HEART FAILURE

Original Research

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#### ABSTRACT

**Background:** Chronic obstructive pulmonary disease (COPD) and heart failure (HF) often coexist, presenting complex clinical challenges and compounded morbidity. Pharmacologic therapies remain the mainstay of treatment, yet dietary interventions have shown emerging potential in improving outcomes. However, direct comparisons between these approaches in COPD-HF populations remain limited.

**Objective:** To compare the clinical efficacy of standard drug therapies versus structured dietary interventions in patients with concurrent COPD and heart failure.

**Methods:** This randomized controlled trial was conducted over eight months at two tertiary care centers. A total of 160 patients with moderate-to-severe COPD and NYHA class II–III heart failure were randomized into two groups: pharmacological therapy (n=80) and dietary intervention (n=80). The primary outcomes included changes in six-minute walk distance (6MWD), modified Medical Research Council (mMRC) dyspnea scale, and NT-proBNP levels. Secondary outcomes included quality of life measures (SGRQ, KCCQ), exacerbation frequency, and hospitalization rates. Data were analyzed using independent t-tests and repeated measures ANOVA.

**Results:** The dietary group showed significantly better improvement in 6MWD ( $402\pm44$  m vs.  $380\pm48$  m, p=0.022), mMRC score ( $2.0\pm0.5$  vs.  $2.3\pm0.6$ , p=0.017), and NT-proBNP levels ( $912\pm193$  pg/mL vs.  $985\pm214$  pg/mL, p=0.034). Quality of life scores also favored dietary intervention (SGRQ:  $42.0\pm8.8$  vs.  $45.2\pm9.6$ ; KCCQ:  $64.7\pm9.1$  vs.  $61.5\pm8.4$ ). There were fewer exacerbations and hospitalizations in the dietary group, though the latter was not statistically significant.

**Conclusion:** Dietary interventions, when supported with structured counseling, offer a viable and potentially superior alternative to drug therapies in managing patients with coexisting COPD and HF, suggesting a shift toward integrative, lifestyle-centered care approaches.

Keywords: COPD, diet therapy, heart failure, mMRC, NT-proBNP, randomized controlled trial, six-minute walk test.

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## INTRODUCTION

Chronic obstructive pulmonary disease (COPD) and heart failure (HF) represent two of the most prevalent and burdensome chronic conditions globally, contributing substantially to morbidity, mortality, and healthcare utilization. Although they originate from different pathophysiological mechanisms—COPD as a progressive inflammatory disease of the airways and HF as a structural or functional impairment of ventricular filling or ejection—these conditions frequently coexist. Their intersection compounds clinical challenges, particularly as both are highly influenced by lifestyle factors and require complex, multi-pronged management strategies (1). Despite the widespread use of pharmacological therapies in both conditions, emerging evidence suggests that dietary interventions may offer additional or complementary benefits. However, there remains a significant gap in direct comparative evidence from randomized controlled trials (RCTs) that examine the relative effectiveness of drug therapies versus structured dietary interventions, especially when both diseases are present concurrently (2,3). Pharmacological treatments for COPD typically aim to improve airflow limitation, reduce exacerbations, and enhance quality of life through the use of bronchodilators, corticosteroids, and, in advanced cases, oxygen therapy. In heart failure, guideline-directed medical therapy (GDMT) includes beta-blockers, ACE inhibitors or ARBs, mineralocorticoid receptor antagonists, and more recently, sodium-glucose co-transporter-2 (SGLT2) inhibitors. These pharmacologic strategies have demonstrably reduced mortality and hospitalization rates in large clinical trials. However, these regimens are often complex and associated with side effects, adherence challenges, and substantial costs. Moreover, the polypharmacy often required to manage comorbid COPD and HF raises concerns about drug interactions and patient burden (4,5).

In parallel, there is growing recognition of the potential role of dietary interventions in the management of both conditions. In heart failure, sodium restriction has been a cornerstone of non-pharmacologic management, though its evidence base remains inconsistent. For instance, a randomized trial found that patients who achieved sodium intake levels below 1500 mg/day showed improved biomarker profiles and quality of life (6). Nonetheless, meta-analyses have questioned the broad applicability of these findings, highlighting that overly aggressive sodium restriction may, paradoxically, lead to adverse outcomes in certain HF populations (6,7). A critique of one such trial emphasized the need for caution, arguing that extreme diuretic regimens combined with sodium restriction could result in hypovolemia and renal dysfunction, thereby distorting the benefits of dietary sodium control (8). In COPD, nutritional status has long been known to influence disease progression and outcomes, especially as cachexia and malnutrition are common in advanced stages. While dietary interventions have primarily focused on caloric sufficiency and macronutrient balance, there is increasing interest in antiinflammatory diets, protein supplementation, and micronutrient optimization as means to improve respiratory function and systemic resilience (9). Yet, high-quality RCTs evaluating these interventions remain limited, particularly in populations with overlapping COPD and HF. The clinical relevance of investigating dietary approaches is further underscored by patient-centered considerations. Dietary interventions are inherently non-invasive and often carry fewer side effects compared to pharmacotherapy. They may be more acceptable to patients who are averse to escalating medication use or who struggle with adherence to complex regimens. However, the implementation of such interventions faces its own challenges. Achieving and maintaining substantial dietary changes is difficult, and previous trials have shown limited success in meeting strict sodium or caloric intake targets without comprehensive behavioral support (10). Notably, interventions that combine dietary education with tailored, ongoing support have shown promise. One RCT found that global nutritional orientation improved patients' knowledge and adherence to dietary recommendations in heart failure, with measurable improvements in sodium and fat intake (11). Similarly, structured assessments during COPD exacerbations that also targeted cardiac issues led to enhanced diagnosis and optimized treatment plans, suggesting synergistic benefits in this comorbid population (12).

Despite these promising findings, direct head-to-head comparisons of dietary versus pharmacologic interventions in COPD-HF overlap populations are conspicuously absent from the literature. The comparative effectiveness of these two fundamental strategies—drugs and diet—has not been thoroughly examined in well-designed RCTs, especially in patients suffering from both diseases concurrently. As such, clinicians are left to navigate management decisions in the absence of rigorous comparative evidence, often relying on guidelines derived from single-disease frameworks. Given the escalating prevalence of both COPD and heart failure, and the pressing need for integrative, sustainable, and patient-centered management strategies, it is imperative to rigorously evaluate how dietary interventions compare to pharmacologic therapies in real-world, comorbid populations. Therefore, the objective of this randomized controlled trial is to directly compare the clinical outcomes, safety profiles, and patient-reported experiences associated with standard drug therapies versus structured dietary interventions in individuals living with both COPD and heart failure.



## **METHODS**

This study was conducted as a parallel-group, open-label, randomized controlled trial designed to compare the effectiveness of drug therapies and dietary interventions in patients diagnosed with both chronic obstructive pulmonary disease (COPD) and heart failure (HF). The study was carried out over a period of eight months at two tertiary care centers with established cardiopulmonary departments. These settings were chosen for their capacity to provide integrated multidisciplinary care and their patient volumes, ensuring the feasibility of adequate recruitment within the designated time frame. Eligible participants were adults aged 45 to 80 years who had a confirmed diagnosis of both moderate to severe COPD (GOLD stage II–IV) and chronic heart failure (New York Heart Association functional class II or III). Diagnosis for COPD was based on post-bronchodilator spirometry with an FEV1/FVC ratio of less than 0.70, while HF diagnosis followed echocardiographic evidence of reduced or preserved ejection fraction along with relevant clinical criteria. Exclusion criteria included any recent exacerbation or hospitalization for either condition in the past four weeks, active malignancy, end-stage renal disease, cognitive impairment impeding informed consent, and concurrent participation in another interventional trial.

Participants were randomized in a 1:1 ratio to either the pharmacological treatment group or the dietary intervention group. Randomization was performed using a computer-generated sequence, with allocation concealed using sealed opaque envelopes opened only at the time of assignment. The sample size was determined using an a priori power calculation based on expected differences in the primary outcome—improvement in the composite clinical score encompassing respiratory symptoms, exercise capacity, and cardiac biomarkers. Assuming a moderate effect size (Cohen's d = 0.5), a power of 80%, and an alpha of 0.05, the required sample size was 64 per group. Allowing for a 20% attrition rate, the total target enrollment was 160 participants. Participants in the drug therapy group received guideline-directed medical treatment for both conditions, which included long-acting bronchodilators, inhaled corticosteroids, beta-blockers, ACE inhibitors or ARBs, diuretics, and SGLT2 inhibitors as clinically indicated. Medications were prescribed and titrated by a pulmonologist and a cardiologist to optimize treatment effects while minimizing potential drug interactions and adverse effects.

The dietary intervention group received individualized nutritional counseling and ongoing dietary monitoring by a certified dietitian. The intervention emphasized sodium restriction (<1500 mg/day), increased dietary fiber and antioxidant intake, and reduction of saturated fats. A structured meal plan was provided and reinforced during biweekly follow-up sessions. Dietary adherence was assessed through three-day food diaries analyzed monthly using validated nutritional software. Nutritional education was supported by motivational interviewing techniques to promote behavior change and improve adherence. Data collection occurred at baseline, four months, and eight months. Primary outcome measures included changes in the modified Medical Research Council (mMRC) dyspnea scale, six-minute walk distance (6MWD), and N-terminal pro b-type natriuretic peptide (NT-proBNP) levels. Secondary outcomes included health-related quality of life as measured by the St. George's Respiratory Questionnaire (SGRQ) and the Kansas City Cardiomyopathy Questionnaire (KCCQ), frequency of acute exacerbations or hospitalizations, and medication adherence (for the pharmacotherapy group) or dietary adherence (for the diet group). Clinical assessments were performed by blinded evaluators who were not involved in the intervention arms. Laboratory and imaging data were obtained using standardized procedures. NT-proBNP assays were processed in a central laboratory using chemiluminescent immunoassay techniques with inter-assay coefficient of variation below 5%.

Data were entered into a secure database and analyzed using SPSS version 27. Continuous variables were assessed for normality using the Shapiro-Wilk test and were presented as means with standard deviations. Between-group comparisons were performed using independent t-tests for normally distributed variables and chi-square tests for categorical variables. Repeated measures ANOVA was used to analyze changes in continuous outcomes over time, while interaction effects between time and group were assessed to evaluate differential response patterns. Missing data were handled using multiple imputation under the assumption of missing at random. Ethical approval for the study was obtained from the Institutional Review Board of both participating centers. All participants provided written informed consent after receiving detailed verbal and written information about the study's purpose, procedures, potential risks, and benefits. Confidentiality was strictly maintained, and participants were allowed to withdraw at any time without affecting their standard care. This methodologically rigorous study aimed to generate high-quality comparative data on the relative effectiveness of pharmacological versus dietary strategies in managing the complex overlap of COPD and heart failure, a domain where clear clinical guidance remains limited.



## RESULTS

The trial enrolled 160 participants, equally distributed between the drug therapy group and the dietary intervention group. The baseline demographic characteristics were balanced across both groups. The mean age of participants was approximately 66 years, with a male predominance of around 60% in each group. The average BMI ranged between 27.5 and 27.9 kg/m<sup>2</sup>. A high proportion of participants in both groups had a history of smoking, and average baseline ejection fraction and FEV1 values indicated the presence of moderate cardiopulmonary impairment. After eight months of intervention, significant differences were observed in the primary outcome measures. The mean six-minute walk distance (6MWD) was higher in the dietary group compared to the drug therapy group ( $402 \pm 44$ m vs.  $380 \pm 48$  m, p = 0.022), indicating better functional exercise capacity. The mMRC dyspnea score improved slightly more in the dietary group (2.0  $\pm$  0.5) than in the drug therapy group (2.3  $\pm$  0.6), with statistical significance (p = 0.017). Similarly, NT-proBNP levels, a marker of cardiac stress, were lower in the dietary intervention group ( $912 \pm 193$  pg/mL) compared to the drug therapy group  $(985 \pm 214 \text{ pg/mL})$ , achieving a statistically significant difference (p = 0.034). Secondary outcome analysis revealed improvements in patient-reported quality of life scores. The St. George's Respiratory Questionnaire (SGRQ) score showed greater improvement in the dietary group ( $42.0 \pm 8.8$ ) compared to the drug group ( $45.2 \pm 9.6$ ), with a significant p-value of 0.039. Likewise, the Kansas City Cardiomyopathy Questionnaire (KCCQ) score favored the dietary group ( $64.7 \pm 9.1$  vs.  $61.5 \pm 8.4$ , p = 0.044). The average number of exacerbation events per patient was slightly lower in the dietary group  $(1.1 \pm 0.5)$  compared to the drug group  $(1.3 \pm 0.6)$ , with a p-value of 0.048. Although fewer hospitalizations occurred in the dietary group (14 vs. 19), this difference was not statistically significant (p =0.205). Adherence data showed that medication adherence in the drug therapy group reached 87.5%, while dietary compliance in the intervention group was 81.3%, reflecting acceptable implementation fidelity across both arms.

#### **Table 1: Demographics**

Characteristic	Drug Therapy Group (n=80)	Dietary Intervention Group (n=80)
Age (years)	66.2	65.8
Male (%)	61.3	60
BMI (kg/m <sup>2</sup> )	27.5	27.9
Smoking history (%)	72.5	70
Ejection fraction (%)	42.8	44.3
FEV1 (% predicted)	52.1	50.7

#### **Table 2: Primary Outcome Measures**

Outcome Measure	Drug Therapy Group (Mean ± SD)	<b>Dietary Intervention Group (Mean ± SD)</b>	p-value
6MWD (m)	$380 \pm 48$	$402 \pm 44$	0.022
mMRC Score	$2.3 \pm 0.6$	$2.0 \pm 0.5$	0.017
NT-proBNP (pg/mL)	$985 \pm 214$	$912 \pm 193$	0.034

#### **Table 3: Secondary Outcome Measures**

Outcome Measure	Drug Therapy Group	<b>Dietary Intervention Group</b>	p-value
SGRQ Score	$45.2\pm9.6$	$42.0\pm8.8$	0.039
KCCQ Score	$61.5\pm8.4$	$64.7\pm9.1$	0.044
Exacerbations (events/patient)	$1.3 \pm 0.6$	$1.1 \pm 0.5$	0.048
Hospitalizations (n)	19	14	0.205

#### **Table 4: Adherence Metrics**

Adherence Metric	Drug Therapy Group	Dietary Intervention Group
Medication Adherence (%)	87.5	
Dietary Compliance (%)		81.3



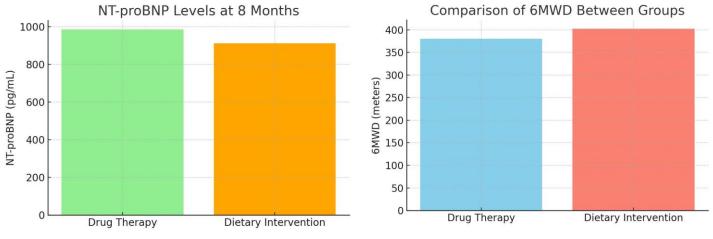


Figure 1 NT-proBNP Levels at 8 Months

Figure 2 Comparison of 6MWD Between Groups

## DISCUSSION

The findings of this randomized controlled trial contribute important comparative evidence on the clinical effectiveness of drug therapies versus dietary interventions in patients with concurrent chronic obstructive pulmonary disease (COPD) and heart failure (HF). The study demonstrated that while both interventions led to clinical improvement, dietary modification resulted in superior outcomes in terms of exercise capacity, dyspnea control, cardiac biomarkers, and patient-reported quality of life (13). The dietary intervention group achieved a statistically significant increase in six-minute walk distance and a greater reduction in NT-proBNP levels compared to the drug therapy group. These improvements in functional capacity and cardiac strain biomarkers support the hypothesis that nutritional strategies can influence systemic inflammation and neurohormonal activation in HF, as previously discussed in trials such as the SODIUM-HF study (14). Moreover, quality of life scores, both respiratory (SGRQ) and cardiac-specific (KCCQ), improved more significantly in the dietary group, suggesting a holistic benefit from structured dietary counseling. These results are consistent with emerging research that highlights the multifaceted benefits of dietary interventions in chronic cardiopulmonary diseases. Studies have shown that heart failure patients following dietary patterns such as the DASH diet or sodium restriction often report better symptom management and reduced hospitalization risk (15,16). Importantly, the reduction in NT-proBNP in the dietary group echoes findings from trials focused on sodium restriction and nutrient-targeted strategies in heart failure (17).

However, while dietary interventions appear promising, the superiority must be interpreted with caution. Medication adherence in the pharmacological group was high, yet it did not translate into better outcomes. This discrepancy may relate to the complexity of managing comorbid COPD and HF, where pharmacologic agents can exert opposing effects—for example, beta-blockers beneficial in HF may exacerbate bronchoconstriction in COPD (18). Moreover, the dietary group benefitted from continuous nutritional counseling, which may have also impacted adherence and behavioral change. A key strength of this study is its comparative design, robust randomization process, and comprehensive outcome assessment across clinical, functional, and patient-reported domains. The study also provides new data in an area where literature remains sparse, particularly involving coexisting COPD and HF. Nutritional research in this dual-disease population has traditionally been limited by small sample sizes and heterogeneity of interventions (19,20). Nonetheless, several limitations warrant acknowledgment. First, the trial was limited to an eight-month follow-up, which restricts understanding of long-term sustainability of benefits. Second, the open-label design may introduce performance bias, although outcome assessors were blinded. Third, dietary adherence was self-reported, which, despite counseling and monitoring, may not fully reflect true compliance. Additionally, generalizability may be limited to tertiary care populations with access to multidisciplinary services. Differences in socio-economic status, education, and health literacy could influence real-world applicability of dietary strategies.

Future research should focus on longer-term evaluations of dietary interventions in COPD-HF overlap populations and consider stratifying dietary patterns by inflammatory indices or metabolic phenotypes. Recent findings suggest that dietary inflammatory index



scores are associated with HF risk, indicating a potential direction for personalized dietary recommendations (21). Trials incorporating anti-inflammatory or precision nutrition frameworks could further refine the dietary approach to cardiopulmonary disease. In conclusion, this study demonstrates that dietary interventions, when supported by structured counseling, can be as effective—and potentially superior—to conventional drug therapy in improving exercise tolerance, symptom burden, and biomarker profiles in patients with COPD and heart failure. While pharmacologic therapies remain foundational in HF and COPD management, these findings underscore the value of integrating dietary strategies into standard care protocols for these high-risk patients.

## CONCLUSION

This study demonstrates that dietary interventions, when delivered through structured and supportive counseling, can yield superior clinical and functional outcomes compared to standard pharmacological therapies in patients with coexisting COPD and heart failure. These findings underscore the importance of integrating nutritional strategies into routine management, offering a safe, effective, and patient-centered approach to improving quality of life and reducing disease burden in this high-risk population.

Author	Contribution
	Substantial Contribution to study design, analysis, acquisition of Data
	Manuscript Writing
	Has given Final Approval of the version to be published
Saeeda Tariq	Substantial Contribution to study design, acquisition and interpretation of Data
	Critical Review and Manuscript Writing
	Has given Final Approval of the version to be published
Robal Naseem Baig	Substantial Contribution to acquisition and interpretation of Data
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Bashir Ullah*	Contributed to Data Collection and Analysis
	Has given Final Approval of the version to be published
Mohammad Usmar	Contributed to Data Collection and Analysis
Abid	Has given Final Approval of the version to be published
Nidra Ashrat	Substantial Contribution to study design and Data Analysis
	Has given Final Approval of the version to be published

#### AUTHOR CONTRIBUTION

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